Lab
5/23/2021

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 628027-75 Rev. AD
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Coulter® 6C Cell Control

Part Number 628027, A59925

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Eurocenter S.A. 22, rue Juste-Oliver, Case Postale 1044, CH-1260 Nyon 1, Switzerland. Telephone +41 (0)22 365 36 11 Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Red; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Hazardous Ingredients

Glutaraldehyde

Neomycin Sulfate

Penicillin-G, sodium salt

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Penicillin-G, sodium salt CAS # 69-57-8 EINECS # 200-710-2 Index # Not available	< 0.1	Xn;R42/43	Resp. Sens. 1 Skin Sens. 1 H317; H334	Resp. Sens. 1 Skin Sens. 1 H317; H334	15, 8
Neomycin Sulfate CAS # 1405-10-3 EINECS # 215-773-1 Index # Not available	< 0.1	Xn;R42/43	Resp. Sens. 1 Skin Sens. 1 H317; H334	Resp. Sens. 1 Skin Sens. 1 H317; H334	15, 8

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Section 3 Composition and Information on Ingredients (Continued)

Glutaraldehyde CAS # 111-30-8 EINECS # 203-856-5 Index # 605-022-00-X	< 0.1	T;R23/25-34-42/43 N;R50	Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Eye Dam. 1 Resp. Sens. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H314; H317; H318; H331; H334; H335; H400	Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Eye Dam. 1 Resp. Sens. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H314; H317; H318; H331; H334; H335; H400	15, 8
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people. Refer section 3.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media

For large fires use extinguishing media suitable for surrounding fire.
In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

5.2 Special hazards arising from the substance or mixture

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Section 5 Fire Fighting Measures (Continued)

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Glutaraldehyde CAS # 111-30-8	0.05 ppm Ceiling (TranslationRequired: activated and inactivated :EndTranslationRequired)
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Glutaraldehyde CAS # 111-30-8	0.1 ppm Peak; 0.42 mg/m3 Peak; 0.05 ppm TWA MAK; 0.21 mg/m3 TWA MAK
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Glutaraldehyde CAS # 111-30-8	0.05 ppm STEL; 0.2 mg/m3 STEL
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.06 @20°C

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Section 9 Physical and Chemical Properties (Continued)

	Color	Red	**Solubility**	
	Transparency	Opaque	**Water**	Miscible
	Odor	Odorless	**Organic**	Not determined
	pH	6.75	**Partition coefficient: n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product.

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Glutaraldehyde CAS # 111-30-8	Inhalation LC50 Rat 0.1 mg/L 4 h; Oral LD50 Rat 66 mg/kg; Dermal LD50 Rat >2000 mg/kg; Dermal LD50 Rabbit 560 µL/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization May produce an allergic reaction in some people. Refer section 3.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Glutaraldehyde CAS # 111-30-8	96 h LC50 Lepomis macrochirus: 7.8-22 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 2.6-4.8 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 7.8-13 mg/L [static]; 96 h LC50 Pimephales promelas: 5.4 mg/L [static]
Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Microtox No information available.

Water Flea

Glutaraldehyde CAS # 111-30-8	48 h EC50 Daphnia magna: 14 mg/L; 48 h EC50 Daphnia magna: 0.56 - 1.0 mg/L [Static]

Fresh Water Algae

Glutaraldehyde CAS # 111-30-8	72 h EC50 Desmodesmus subspicatus: 0.61 mg/L; 96 h EC50 Desmodesmus subspicatus: 0.84 mg/L

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Section 12 Ecological Information (Continued)

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

5-Fluorouracil is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Tetracycline Hydrochloride is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Methanol is listed.

Sodium Hydroxide is listed.

Sodium Phosphate, Dibasic is listed.

Sodium Azide is listed.

California Proposition 65

5-Fluorouracil has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Tetracycline Hydrochloride has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

5-Fluorouracil is listed.

Methanol is listed.

Glutaraldehyde is listed.

Sodium Hydroxide is listed.

Sodium Phosphate, Dibasic is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

5-Fluorouracil is listed.
Tetracycline Hydrochloride is listed.
Methanol is listed.
Glutaraldehyde is listed.
Sodium Hydroxide is listed.
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

Pennsylvania RTK

5-Fluorouracil is listed.
Methanol is listed.
Glutaraldehyde is listed.
Sodium Hydroxide is listed.
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Methanol
Citric Acid
Glutaraldehyde
Iodoacetamide
Sodium Hydroxide
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Xn - Harmful
R23/25 Toxic by inhalation and if swallowed.
R34 Causes burns.
R42/43 May cause sensitization by inhalation and skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50 Very toxic to aquatic organisms.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Resp. Sens. 1 - Respiratory Sensitization Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: C59062: Version AA
Issue Date (year/month/day) 2020/04/20

Product Information

Product Name	Access SARS-CoV-2 IgG
Part Number	C58961
Series Name	ACCESS

Components

Description

SARS-CoV-2 IgG Particles (Compartment R1a)
SARS-CoV-2 IgG Conjugate Diluent (Compartment R1b)
SARS-CoV-2 IgG Conjugate (Compartment R1c)
SARS-CoV-2 IgG Ancillary Diluent (Compartment R1d)
SARS-CoV-2 IgG Ancillary Diluent (Compartment R1e)

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: C59062 Version AA
Issue Date (year/month/day) 2020/04/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG Particles (Compartment R1a)

Part Number Component of P/N C58961

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Brown; Opaque; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8: 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8: 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8: 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8: Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8: 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.044
Color	Brown	**Solubility**	
Transparency	Opaque	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	7.0	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 56-81-5	Glycerol

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 56-81-5 Glycerol

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 56-81-5 Glycerol

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2020/04/20
Document ID: C59062
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C

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Section 16 Other Information (Continued)

	Skin Sens. 1A - Skin Sensitization Category 1A H300 - Fatal if swallowed. H301 - Toxic if swallowed. H310 - Fatal in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H318 - Causes serious eye damage. H330 - Fatal if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: C59062 Version AA
Issue Date (year/month/day) 2020/04/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG Conjugate Diluent (Compartment R1b)

Part Number Component of P/N C58961

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	6.0	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration
CAS # 7646-85-7	Zinc Chloride	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide
CAS # 7646-85-7	Zinc Chloride

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 7646-85-7	Zinc Chloride

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 7646-85-7 Zinc Chloride

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 7646-85-7 Zinc Chloride

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2020/04/20
Document ID: C59062
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C

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Section 16 Other Information (Continued)

	Skin Sens. 1A - Skin Sensitization Category 1A H300 - Fatal if swallowed. H301 - Toxic if swallowed. H310 - Fatal in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H318 - Causes serious eye damage. H330 - Fatal if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: C59062 Version AA
Issue Date (year/month/day) 2020/04/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG Conjugate (Compartment R1c)

Part Number Component of P/N C58961

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	6.0	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration
CAS # 7646-85-7	Zinc Chloride	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide
CAS # 7646-85-7	Zinc Chloride

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 7646-85-7	Zinc Chloride

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 7646-85-7 Zinc Chloride

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 7646-85-7 Zinc Chloride

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2020/04/20
Document ID: C59062
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C

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Section 16 Other Information (Continued)

	Skin Sens. 1A - Skin Sensitization Category 1A
	H300 - Fatal if swallowed.
	H301 - Toxic if swallowed.
	H310 - Fatal in contact with skin.
	H314 - Causes severe skin burns and eye damage.
	H317 - May cause an allergic skin reaction.
	H318 - Causes serious eye damage.
	H330 - Fatal if inhaled.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA DGR - International Air Transport Association Dangerous Goods Regulation
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: C59062 Version AA
Issue Date (year/month/day) 2020/04/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG Ancillary Diluent (Compartment R1d)

Part Number Component of P/N C58961

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Aquatic Hazard Long term, Category 3
Eye Irritation Category 2

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3
Eye Irritation Category 2

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Ethoxylated lauryl alcohol

Pictogram

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.2.5% of product contains ingredients of unknown hazards to the aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

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Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Ethoxylated lauryl alcohol CAS # 9002-92-0 EINECS # Not available Index # Not available	1 - < 3	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. If pain or irritation occurs, obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
May cause serious eye irritation.
May cause mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.018
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg
Ethoxylated lauryl alcohol CAS # 9002-92-0	Oral LD50 Rat 1 g/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity

Not based on available data.

Skin Corrosion/Irritation

May cause mild skin irritation.

Serious eye damage/eye irritation

May cause serious eye irritation.

Respiratory/skin sensitization

May cause sensitization by skin contact.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not based on available data.

Reproductive Toxicity

Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2020/04/20
Document ID: C59062
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1

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Section 16 Other Information (Continued)

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1A - Skin Sensitization Category 1A
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: C59062 Version AA
Issue Date (year/month/day) 2020/04/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG Ancillary Diluent (Compartment R1e)

Part Number Component of P/N C58961

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Aquatic Hazard Long term, Category 3
Eye Irritation Category 2

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3
Eye Irritation Category 2

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Ethoxylated lauryl alcohol

Pictogram

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.2.5% of product contains ingredients of unknown hazards to the aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

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Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Ethoxylated lauryl alcohol CAS # 9002-92-0 EINECS # Not available Index # Not available	1 - < 3	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. If pain or irritation occurs, obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
May cause serious eye irritation.
May cause mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.018
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid — Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg
Ethoxylated lauryl alcohol CAS # 9002-92-0	Oral LD50 Rat 1 g/kg

Primary Routes of Exposure — Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity — Not based on available data.

Skin Corrosion/Irritation — May cause mild skin irritation.

Serious eye damage/eye irritation — May cause serious eye irritation.

Respiratory/skin sensitization — May cause sensitization by skin contact.

Carcinogenicity — No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity — Not based on available data.

Reproductive Toxicity — Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2020/04/20
Document ID: C59062
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1

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Section 16 Other Information (Continued)

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1A - Skin Sensitization Category 1A
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Document ID: C75582: Version AA
Issue Date (year/month/day) 2021/03/16

Product Information

Product Name	ACCESS SARS-CoV-2 IgG (1st IS) Calibrator
Part Number	C74340
Series Name	ACCESS

Components

Description	SARS-CoV-2 IgG (1st IS) S0 SARS-CoV-2 IgG (1st IS) S1 - S5

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: C75582 Version AA
Issue Date (year/month/day) 2021/03/16

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG (1st IS) S0

Part Number Component of P/N C74340

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.02
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	8.0	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 56-81-5	Glycerol

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 56-81-5 Glycerol

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 56-81-5 Glycerol

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2021/03/16
Document ID: C75582
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C

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Section 16 Other Information (Continued)

	Skin Sens. 1A - Skin Sensitization Category 1A H300 - Fatal if swallowed. H301 - Toxic if swallowed. H310 - Fatal in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H318 - Causes serious eye damage. H330 - Fatal if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: C75582 Version AA
Issue Date (year/month/day) 2021/03/16

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name SARS-CoV-2 IgG (1st IS) S1 - S5

Part Number Component of P/N C74340

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.02
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	8.0	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 56-81-5	Glycerol

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 56-81-5 Glycerol

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide
CAS # 56-81-5 Glycerol

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Document version and issue/revision date

Issue Date (year/month/day) 2021/03/16
Document ID: C75582
Version: AA

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C

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Section 16 Other Information (Continued)

	Skin Sens. 1A - Skin Sensitization Category 1A H300 - Fatal if swallowed. H301 - Toxic if swallowed. H310 - Fatal in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H318 - Causes serious eye damage. H330 - Fatal if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 472515-75 Rev. AH
Revised (year/month/day) 2016/10/19

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Alkaline Buffer

Part Number 472515

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pink; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3	**Advice for fire fighters**	
	Protective Equipment	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1	**Personal precautions, protective equipment and emergency procedures**	
	Personal Precautions	No special precautions are necessary. Use good laboratory procedures.
6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	No special precautions are necessary; use good laboratory procedures.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at Room Temperature, as directed on the Product Label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**Specific end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	None established
	DFG MAK	None established
	Ireland	None established
	IOELVs	None established
	NIOSH	None established
	Japan	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈0.997 @20°C
Color	Pink	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.6-9.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Not classified based on available data.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard	Not classified based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Isopropyl Alcohol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Phenolphthalein is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

1,4-Dioxane is listed.

Ethylene Oxide is listed.

California Proposition 65

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Phenolphthalein has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

1,4-Dioxane is listed.

Ethylene Oxide is listed.

Isopropyl Alcohol is listed.

New Jersey Dept. of Health RTK List

1,4-Dioxane is listed.

Ethylene Oxide is listed.

Isopropyl Alcohol is listed.

Phenolphthalein is listed.

Pennsylvania RTK

1,4-Dioxane is listed.

Ethylene Oxide is listed.

Isopropyl Alcohol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Polyoxyethylated Octyl Phenol
1,4-Dioxane
Ethylene Oxide
Isopropyl Alcohol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the storage temperature.
Updated Section 4, 8, 11.
Updated Section 7.
Updated Section 16.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration

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Section 16 Other Information (Continued)

PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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SECTION 1: Identification of the substance/mixture and of the company/ undertaking

· **1.1 Product identifier**

· **Trade name: Lens Solution**

· **Article number:** F24833-0000, F24835-0000, F24842-0001
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Glass Cleaner

· **1.3 Details of the supplier of the Safety Data Sheet**
· **Manufacturer/Supplier:**
Bel-Art Products
661 Route 23
Wayne, NJ 07470
(800) 423-5278

· **1.4 Emergency telephone number:** +1 (800) 457-4280

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Classifications listed also are applicable to the OSHA GHS Hazard Communication Standard (29CFR1910.1200).

Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xi; Irritant

R36: Irritating to eyes.
R67: Vapours may cause drowsiness and dizziness.
· **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
The classification is in accordance with the latest editions of international substances lists, and is supplemented by information from technical literature and by information provided by the company.
· **Additional information:**
There are no other hazards not otherwise classified that have been identified.
0 percent of the mixture consists of component(s) of unknown toxicity

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· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is additionally classified and labelled according to the Globally Harmonized System within the United States (GHS).
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
sodium 2-(2-dodecyloxyethoxy)ethyl sulphate
· **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
· **Precautionary statements**

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.

· **Hazard description:**
· **WHMIS-symbols:**
D2B - Toxic material causing other toxic effects

· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS Long Term Health Hazard Substances**
None of the ingredients are listed.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 67-63-0 EINECS: 200-661-7 Index number: 603-117-00-0	propan-2-ol Xi R36; F R11 R67 Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	5-15%
CAS: 5131-66-8 EINECS: 225-878-4 Index number: 603-052-00-8	3-butoxypropan-2-ol Xi R36/38 Skin Irrit. 2, H315; Eye Irrit. 2, H319	1-5%
CAS: 3088-31-1	sodium 2-(2-dodecyloxyethoxy)ethyl sulphate Skin Irrit. 2, H315; Skin Sens. 1, H317	1-5%

· **Additional information:**
For the listed ingredients, the identity and exact percentages are being withheld as a trade secret.
For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:**
Immediately rinse with water.
If skin irritation continues, consult a doctor.
· **After eye contact:**
Remove contact lenses if worn.
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; call for medical help immediately.
· **4.2 Most important symptoms and effects, both acute and delayed**
Dizziness
Coughing
Allergic reactions
Irritant to eyes.
Acidosis
· **Hazards** No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
Medical supervision for at least 48 hours.

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Treat skin and mucous membrane with antihistamine and corticoid preparations.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
· **For safety reasons unsuitable extinguishing agents:** None.
· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
· **5.3 Advice for firefighters**
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.
· **Additional information** Use large quantities of foam as it is partially destroyed by the product.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Use respiratory protective device against the effects of fumes/dust/aerosol.
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
Product forms slippery surface when combined with water.
· **6.2 Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Dilute with plenty of water.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Pick up mechanically.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
Send for recovery or disposal in suitable receptacles.
· **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
Prevent formation of aerosols.
Use only in well ventilated areas.
· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Store away from foodstuffs.

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· **Further information about storage conditions:**
Store in cool, dry conditions in well sealed receptacles.
Keep container tightly sealed.
· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
67-63-0 propan-2-ol	
PEL (USA)	Long-term value: 980 mg/m³, 400 ppm
REL (USA)	Short-term value: 1225 mg/m³, 500 ppm Long-term value: 980 mg/m³, 400 ppm
TLV (USA)	Short-term value: 984 mg/m³, 400 ppm Long-term value: 492 mg/m³, 200 ppm BEI
EL (Canada)	Short-term value: 400 ppm Long-term value: 200 ppm
EV (Canada)	Short-term value: 400 ppm Long-term value: 200 ppm

· **DNELs** No further relevant information available.
· **PNECs** No further relevant information available.

· **Ingredients with biological limit values:**	
67-63-0 propan-2-ol	
BEI (USA)	40 mg/L Medium: urine Time: end of shift at end of workweek Parameter: Acetone (background, nonspecific)

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
· **Respiratory protection:**
Not required under normal conditions of use.
For large spills, respiratory protection may be advisable.

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· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**

Safety glasses

· **Body protection:** Protective work clothing

· **Limitation and supervision of exposure into the environment**
No further relevant information available.

· **Risk management measures**
See Section 7 for additional information.
No further relevant information available.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Liquid
Colour:	Whitish
· **Odour:**	Like alcohol
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	Not Determined.
Boiling point/Boiling range:	82 °C (180 °F)
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Auto/Self-ignition temperature:**	425 °C (797 °F)

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· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not self-igniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure at 20 °C (68 °F):**	43 hPa (32 mm Hg)
· **Density at 20 °C (68 °F):**	0,97 g/cm³ (8,095 lbs/gal)
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with water:**	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
· **10.3 Possibility of hazardous reactions** Reacts with strong oxidising agents.
· **10.4 Conditions to avoid** Store away from oxidising agents.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values relevant for classification:** None.
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitisation:** Sensitisation possible through skin contact.
· **Subacute to chronic toxicity:** No further relevant information available.

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· **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
Inhalation of concentrated vapours as well as oral intake will lead to anaesthesia-like conditions and headache, dizziness, etc.
Toxic and/or corrosive effects may be delayed up to 24 hours.
· **Acute effects (acute toxicity, irritation and corrosivity):**
Vapours have narcotic effect.
Irritating to eyes.
· **Sensitisation:** May cause an allergic skin reaction.
· **Repeated dose toxicity:** Repeated exposures may result in skin and/or respiratory sensitivity.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Small amounts may be diluted with plenty of water and washed away. Dispose of larger amounts in accordance with Local Authority requirements.
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes. Residual materials should be treated as hazardous.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

· **14.1 UN-Number**
· **DOT, ADR, ADN, IMDG, IATA** Not Regulated
· **14.2 UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** Not Regulated
· **14.3 Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**
· **Class** Not Regulated
· **14.4 Packing group**
· **DOT, ADR, IMDG, IATA** Not Regulated
· **14.5 Environmental hazards:**
· **Marine pollutant:** No
· **14.6 Special precautions for user** Not applicable.
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
· **UN "Model Regulation":** -

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **United States (USA)**
· **SARA**

· **Section 355 (extremely hazardous substances):**
None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

67-63-0	propan-2-ol

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **Proposition 65 (California):**

· **Chemicals known to cause cancer:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients are listed.

· **Carcinogenic Categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients are listed.

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· **IARC (International Agency for Research on Cancer)**

67-63-0	propan-2-ol	3

· **TLV (Threshold Limit Value established by ACGIH)**

67-63-0	propan-2-ol	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed.

· **Canada**

· **Canadian Domestic Substances List (DSL)**

All ingredients are listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients are listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

67-63-0	propan-2-ol

· **Other regulations, limitations and prohibitive regulations**
This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

· **Substances of very high concern (SVHC) according to REACH, Article 57**

None of the ingredients are listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

R11 Highly flammable.
R36 Irritating to eyes.
R36/38 Irritating to eyes and skin.
R67 Vapours may cause drowsiness and dizziness.

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
WHMIS: Workplace Hazardous Materials Information System (Canada)
VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· **Sources**

SDS Prepared by:
ChemTel Inc.
1305 North Florida Avenue
Tampa, Florida USA 33602-2902
Toll Free North America 1-888-255-3924 Intl. +01 813-248-0573
Website: www.chemtelinc.com

Apo A1 and B Calibrator

SAFETY DATA SHEET

Document ID: ODR3022-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Apo A1 and B Calibrator

Part Number ODR3022

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Lismeehan O'Callaghan's Mills Co. Clare Ireland Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light brown; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Apo A1 and B Calibrator

SAFETY DATA SHEET

Document ID: ODR3022-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Light brown	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0 - 8.0 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the label elements in Sec. 2.2.

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated hazardous ingredients in Section 3.

Updated Section 15 Regulatory Information.

Updated section 4, 6, 8, 10, 11, 14, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12

Last Revision Date (year/month/day) 2015/03/20

Document ID: ODR3022-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

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Apo A1 and B Calibrator

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Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information (Continued)

US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6143-75: Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Product Information

Product Name	APO B
Part Number	OSR6143

Components

Description	Apo B R1 Apo B R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6143-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Apo B R1

Part Number Component of P/N OSR6143

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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APO B
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Last Revision Date (year/month/day) 2015/03/20

Section 2 Hazards (Continued)

2.2 Label Elements — **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

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Document ID: OSR6143-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.05
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	7.4	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	250°C (482°F)	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.

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Section 12 Ecological Information (Continued)

	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

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14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

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SAFETY DATA SHEET

Section 15 Regulatory Information (Continued)

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 3, 4, 6 - 8, 11, 14 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20
Document ID: OSR6143-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances

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Section 16 Other Information (Continued)

SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: OSR6143-75 Version 04
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Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Apo B R2

Part Number Component of P/N OSR6143

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light orange; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Light orange	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the label elements in Sec. 2.2.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated hazardous ingredients in Section 3.
Updated Section 3 - 8, 10, 11, 14 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20
Document ID: OSR6143-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
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IARC - International Agency for Research on Cancer
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ICAO - International Civil Aviation Organization
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NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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GHS (United States of America , Canada , Mexico)

Safety Data Sheet

Aptima Urine Specimen Collection

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product Identifier

Product Name Aptima Urine Specimen Collection

Recommended use of the chemical and restrictions on use

Specific use(s) Aptima Urine Collection Kit, Aptima Urine Specimen Transport Tubes

Recommended Use In vitro diagnostic

Details of the supplier of the safety data sheet

United States of America Supplier
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362

Canadian Supplier
Hologic Canada Limited
130 Spadina Avenue, Suite 401
Toronto, ON, M5V-2L4
Canada
1-877-209-7192

Emergency Telephone - United States of America
24 Hour Emergency Phone Number Chemtrec, U.S. and Canada 1-800-424-9300; Chemtrec International + 1-703-741-5970

For further information, please contact: MolecularSupport@hologic.com

SECTION 2: Hazards identification

Classification
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Emergency Overview

Label Elements

ERG Code

Hazards not otherwise classified (HNOC)
H402 - Harmful to aquatic life.

12.14% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 3: Composition/information on ingredients

Substances
Not applicable

Mixtures

Mixtures

OSHA Hazard Classification
The product contains no substances, which at their given concentration, are considered to be hazardous to health.

SECTION 4: First aid measures

First aid measures

Eye contact — In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If symptoms persist, call a physician.

Skin Contact — Wash skin with soap and water. If symptoms persist, call a physician.

Inhalation — Remove to fresh air. If symptoms persist, call a physician.

Ingestion — Clean mouth with water and drink afterwards plenty of water. If symptoms persist, call a physician.

Indication of any immediate medical attention and special treatment needed

Note to physicians — Treat symptomatically.

SECTION 5: Firefighting measures

Flammability — Not flammable.

Suitable Extinguishing Media — Use extinguishing agent suitable for type of surrounding fire.

Protective equipment and precautions for firefighters — As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions — Use personal protective equipment as required.

Environmental precautions — See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment — Cover with absorbent or contain.

Methods for cleaning up — Soak up with inert absorbent material. Dispose of contents/containers in accordance with local regulations.

SECTION 7: Handling and storage

Precautions for safe handling — Avoid prolonged contact with eyes, skin, and clothing. No known effects under normal use conditions.

Advice on safe handling — Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Wash hands thoroughly after handling. Use personal protection recommended in Section 8.

Conditions for safe storage, including any incompatibilities

Storage — Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.

SECTION 8: Exposure Controls/Personal Protection.

Exposure Guidelines
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

United States of America

None

Canada

None

Mexico

None

Appropriate engineering controls

Engineering Controls Provide adequate ventilation. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin and body protection	Wear suitable protective clothing.
Hand Protection	Wear protective gloves.
Respiratory protection	Not applicable

Other Information

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical State @20°C	Liquid
Color	Colorless
Odor	No information available
Odor threshold	No information available

Property	**Values**
pH	~ 7.5
Melting point/freezing point	
Boiling point / boiling range	No information available
Flash point	
Method	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper flammability limits	No information available
Lower flammability limit	No information available
Vapor pressure	No information available
Vapor density	No information available
Relative density	No information available
Water solubility	No information available
Solubility(ies)	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available
Oxidizing properties	No information available

SECTION 10: Stability and reactivity

Reactivity None under normal use conditions.

Stability Stable under normal conditions.

Possibility of Hazardous Reactions None under normal use conditions.

Hazardous polymerization None under normal use conditions.

Conditions to avoid None under normal use conditions.

Incompatible materials. None under normal use conditions.

Hazardous Decomposition Products None under normal use conditions.

Materials to avoid None under normal use conditions.

SECTION 11: Toxicological information

Information on likely routes of exposure

Product Information Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation None under normal use conditions.
Eye contact None under normal use conditions.
Skin Contact None under normal use conditions.
Ingestion None under normal use conditions.

Component name	LD50/oral/rat - NO UNITS (Wizards mg/kg)	LD50/dermal/rat - NO UNITS (Wizards mg/kg)	Inhalation LC50
Ammonium Sulfate 7783-20-2	= 2000 mg/kg (Rat)	-	-
Lithium Hydroxide, Anhydrous 1310-65-2	= 120 mg/kg (Rat)	-	= 960 mg/m³ (Rat) 4 h

Information on toxicological effects

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.
Serious eye damage/eye irritation No information available.
Sensitization No information available.
Germ cell mutagenicity No information available.
Carcinogenicity No information available.

Reproductive toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 12.14% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .
ATEmix (inhalation-dust/mist) 191.4 mg/l

SECTION 12: Ecological information

Ecotoxicity
20 - 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Component name	Algae/aquatic plants	Fish	Toxicity to	Crustacea

			microorganisms	
Ammonium Sulfate 7783-20-2				14: 48 h Daphnia magna mg/L LC50

Persistence and degradability No information available.

Bioaccumulation No information available.

Mobility No information available.

Other adverse effects No information available.

SECTION 13: Disposal Considerations.

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Waste from Residues / Unused Products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

SECTION 14: Transport information

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG Not regulated

SECTION 15: Regulatory information

International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	X	X
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	-
HEPES 7365-45-9	Present	X	X	X
Ammonium Sulfate 7783-20-2	Present	X	X	X
Lithium Hydroxide, Anhydrous 1310-65-2	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	-	X	X	Present
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	Present
HEPES 7365-45-9	-	X	X	-

Aptima Urine Specimen Collection

Ammonium Sulfate 7783-20-2	Present	X	X	Present
Lithium Hydroxide, Anhydrous 1310-65-2	Present	X	X	Present

Legend
X - Present
- Not Listed
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Component name	CAS No	%	SARA 313 - Threshold Values %
Ammonium Sulfate - 7783-20-2	7783-20-2	1 - 5	1.0

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Component name	New Jersey	Massachusetts	Pennsylvania
Ammonium Sulfate 7783-20-2		X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

International Regulations

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

WHMIS Hazard Class

Non-controlled

Mexico
No information available

SECTION 16: Other information

Revision Date 11-Jul-2018

Version 3

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Kit SDS Cover Sheet

Document ID: OSR6109: Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Product Information

Product Name	AST
Part Number	OSR6209, OSR6009, OSR6109, OSR6609

Components

Description	AST R1 AST R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6109 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name AST R1

Part Number Component of P/N OSR6009, OSR6109, OSR6209, OSR6609

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light yellow; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Tris(hydroxymethyl)– aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	5 - 8	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

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AST
AST R1

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan	None established
Sweden (AFS 2015:7 and amendments)	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.12
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	8.2 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	Metals and metallic compounds
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

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Section 11 Toxicological Information (Continued)

Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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		To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1 Updated E-mail address in Sec. 1.3. Updated Section 8, 11, 15, 16.	

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Global SDS – English

Section 16 Other Information (Continued)

Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08
Document ID: OSR6109
Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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AST
AST R1

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Document ID: OSR6109 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name AST R2

Part Number Component of P/N OSR6009, OSR6109, OSR6209, OSR6609

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements — **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	10.2 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.

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Section 12 Ecological Information (Continued)

	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

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14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

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Section 15 Regulatory Information (Continued)

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated E-mail address in Sec. 1.3.

Updated Section 8, 11, 15, 16.

Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28

Last Revision Date (year/month/day) 2017/05/08

Document ID: OSR6109
Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

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AST
AST R2

SAFETY DATA SHEET

Document ID: OSR6109 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 16 Other Information (Continued)

OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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1. Product and Company Identification

PRODUCT NAME: AUVI-Q™ (epinephrine injection, USP)
0.3 mg or 0.15 mg Auto-Injector

Substance name: Epinephrine

Supplier:
Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec):	**(703) 527-3887**
US Customer Service	**(800) 207-8049**
24-Hour Emergency, sanofi-aventis US:	**(908) 981-5550**

Product use: Pharmaceutical device.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification (epinephrine solution):
Acute toxicity - oral, Category 4
Acute toxicity - dermal, Category 4
Acute toxicity - inhalation, Category 4

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, epinephrine:

Signal Word: Warning

Hazard Statement(s): Harmful if swallowed, if inhaled or in contact with skin.

Symbol(s): Exclamation mark

Precautionary Statement(s):

- Prevention: Avoid breathing spray. Use only in a well-ventilated area. Wear protective gloves. Wash hands thoroughly after handling. Do not eat, drink or smoke while using this product.

- Response: If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center if you feel unwell. If swallowed: Call a poison center if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water and soap. Take off contaminated clothing and wash it before reuse. Call a poison center if you feel unwell.

- Storage: Store locked up.

- Disposal: Dispose of contents and container in accordance with applicable regional, national and local laws and regulations.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

---

3. Composition/Information on Ingredients

Chemical Name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
(-)-3,4-Dihydroxy-α-[(methylamino)methyl] benzyl alcohol	Epinephrine	51-43-4	0.11 %
Sulfurous acid, monosodium salt	Sodium bisulfite	7631-90-5	0.2 %
Sodium chloride	Sodium chloride	7647-14-5	1.2 %
Hydrochloric acid		7647-01-0	Trace (used for pH adjustment
Water	Water	7732-18-5	Balance (> 98%)

The device contains a small amount (about 1 mL) of inert gas (argon, CAS # 7440-37-1).

---

4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with product, immediately flush skin with plenty of soap and water. Remove contaminated clothing and shoes. Call a poison center if you feel unwell.

Ingestion: If swallowed, call a poison center. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention. Call a poison center if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties.

4.3 Indication of any immediate medical attention and special treatment needed

In case of accidental injection to the digits, hands, or feet, treatment should be directed at vasodilation. See package insert for additional information.

---

5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Do not eat, smoke or drink while handling product. Wash hands thoroughly after handling.

7.2 Conditions for Safe Storage

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Store at 20 – 25^{o}C (68 – 77^{o} F). Do not refrigerate.

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure band, epinephrine: 1 - 10 micrograms/m^3, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

The following information is for the epinephrine product solution unless otherwise noted:

Appearance: Clear, colorless liquid.
Odor: No data available.
Odor threshold: No data available.
pH: 2.2 – 5.0
Freezing point: No data available.
Initial boiling point/boiling point range: No data available.
Flash point: No data available.
Evaporation rate: No data available.
Flammability: No data available.
Upper/lower flammability or explosive limits: No data available.
Vapor pressure: No data available.
Vapor density: No data available.

Relative density: 1.006 g/cm3 at 20 °C
Solubility: No data available.
Partition coefficient: n-octanol/water: No data available.
Auto-ignition temperature: No data available.
Decomposition temperature: No data available.
Viscosity: No data available.

---

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

---

11. Toxicological Information

The following information is for the active ingredient epinephrine unless otherwise noted:

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties.

Effects of short-term (acute) exposure: Overexposure to epinephrine may cause serious and potentially fatal cardiovascular effects, including elevated arterial pressure, pulmonary edema, and transient bradycardia followed by tachycardia. See package insert.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD50):
Epinephrine:
Oral LD50, rat: 4 mg/kg
Dermal LD50, rat: 62 mg/kg.
Inhalation LD50, rat: 0.00125 mg/l

Sodium bisulfite:
Oral LD50, rat: 2,000 mg/kg.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: Sodium bisulfite: may cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons.

Epinephrine: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: Long-term studies to evaluate the carcinogenic potential of epinephrine have not been evaluated.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Epinephrine was teratogenic in rabbits, mice and hamsters. Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal dose of 1.2 mg/kg/day for two to three days), in mice at approximately 7 times the maximum daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 1 mg/kg/day for 10 days), and in hamsters at approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 0.5 mg/kg/day for 4 days).

These effects were not seen in mice at approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

Mutagenicity: Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

Aspiration hazard: No data available.

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12. Ecological Information

The following information is for the active ingredient epinephrine unless otherwise noted:

12.1. Ecotoxicity

Acute invertebrate toxicity: EC50 = 40.0 mg/L
Species: Daphnia magna
Duration of test: 24 hours

Acute invertebrate toxicity: EC50 = 31.7 mg/L
Species: Daphnia magna
Duration of test: 48 hours

12.2. Persistence and degradability

Biological degradability: approx. 41%; not readily biodegradable.
Duration of test: 28 days

12.3. Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

No data available

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Epinephrine (CAS # 51-43-4) is a RCRA listed hazardous waste, code P042.

The device contains two lithium button cell batteries and a small steel gas cell containing about 1 mL of argon.

California regulations: This product uses batteries containing perchlorate material.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

AUVI-Q™ contains two lithium metal batteries and should be shipped according to the current regulatory requirements applicable for lithium metal batteries contained in equipment and based on the mode of transport.

15. Regulatory Information

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.
Massachusetts Right-To-Know List: Not listed.
New Jersey Right-To-Know List: Not listed.
Pennsylvania Right-To-Know List: Not listed.

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16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms
CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

Date Prepared: September 29, 2015

Second version.

Kit SDS Cover Sheet

Doc. ID: 33000-75: Rev. AG
Revised (year/month/day) 2015/04/15

Product Information

Product Name	VITAMIN B_{12}
Part Number	33000
Series Name	ACCESS®

Components

Description

Particles (Compartment R1a)
Neutralizing Solution (Compartment R1b)
Conjugate (Compartment R1c)
Denaturing Reagent (Compartment R1d)
Reducing Reagent (Compartment R1e)

Transport Information

Shipping Information	**IATA**	**IMDG**	**US DOT**	**European ADR**	**Canadian TDG**
UN/ID Number	3316	3316	3316	3316	3316
Shipping Name	Chemical kit				
Hazard Class	9 Miscellaneous Dangerous Goods	9 Miscellaneous dangerous substances and articles	9 Miscellaneous hazardous material	9 Miscellaneous dangerous substances and articles	9 Miscellaneous Dangerous Goods
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	M11	Not applicable
Packing Group	II	II	II	II	II
Special Provisions	A44	251; 340	15	251, 340	65
Additional information					
IATA ERG Code	9L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-P	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	171	Not applicable	171
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33000-75 Rev. AG
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Particles (Compartment R1a)

Part Number Component of P/N 33000

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Mild odor	**Organic**	Not determined
pH	8.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Global SDS – English

Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.

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Section 16 Other Information (Continued)

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33000-75 Rev. AG
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Neutralizing Solution (Compartment R1b)

Part Number Component of P/N 33000

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellow; Clear; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Borate Decahydrate

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.

P280 Wear protective gloves, protective clothing and eye/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Borate Decahydrate CAS # 1303-96-4 EINECS # 237-560-2 Index # 005-011-01-1	1 - 3	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Borate Decahydrate CAS # 1303-96-4	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

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Section 8 Exposure Controls and Personal Protection (Continued)

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA

Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.017 @20°C
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	6.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Borate Decahydrate CAS # 1303-96-4	Oral LD50 Rat 2660 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	May damage fertility or the unborn child.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability — Not determined for the product.

12.3 Bioaccumulation — Not determined for the product.

12.4 Mobility in soil — Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects — This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Methanol is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

California Proposition 65

Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

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Section 15 Regulatory Information (Continued)

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Azide is listed.

Pennsylvania RTK

Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Methanol
Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Sodium Borate Decahydrate
Sodium Azide

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Section 15 Regulatory Information (Continued)

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Repr. Cat. 2 - Toxic for Reproduction Category 2
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 May impair fertility.
R61 May cause harm to unborn child.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 3 - Skin Irritation Category 3
Repr. 1B - Toxic to Reproductive Category 1B
H300 - Fatal if swallowed.
H303 - May be harmful if swallowed
H313 - May be harmful In contact with skin
H316 - Causes mild skin irritation.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33000-75 Rev. AG
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Conjugate (Compartment R1c)

Part Number Component of P/N 33000

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Translucent; Liquid; Slight odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.088 @20°C
Color	Colorless	**Solubility**	
Transparency	Translucent	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Slight odor	**Organic**	Not determined
pH	8.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Global SDS – English

Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.

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Section 16 Other Information (Continued)

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33000-75 Rev. AG
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Denaturing Reagent (Compartment R1d)

Part Number Component of P/N 33000

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Slight almond odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R36/38

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hydroxide

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Hydroxide CAS # 1310-73-2 EINECS # 215-185-5 Index # 011-002-00-6	1 - 3	C;R 35	Eye Dam. 1 Skin Corr. 1A H314; H318	Eye Dam. 1 Skin Corr. 1A H314; H318	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open and obtain medical attention immediately.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Exposure may cause irritation or burns to respiratory tract, skin, and eyes. Corrosive effects may be delayed.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

If eye irritation persists: Get medical advice/attention.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

To maintain product quality, store according to the instructions in the product labeling.

Store at 2 to 10°C, as directed on the product label.

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sodium Hydroxide
CAS # 1310-73-2: 2 mg/m3 TWA

ACGIH

Sodium Hydroxide
CAS # 1310-73-2: 2 mg/m3 Ceiling

DFG MAK: None established

Ireland

Sodium Hydroxide
CAS # 1310-73-2: 2 mg/m3 STEL

IOELVs: None established

NIOSH

Sodium Hydroxide
CAS # 1310-73-2: 10 mg/m3 IDLH

Japan: None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight almond odor	**Organic**	Not determined
pH	13.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hydroxide CAS # 1310-73-2	Dermal LD50 Rabbit 1350 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Contact may cause skin burns.

Serious eye damage/eye irritation

Contact may cause serious eye damage.

Respiratory/skin sensitization

No data available.

Carcinogenicity

This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hydroxide CAS # 1310-73-2	96 h LC50 Oncorhynchus mykiss: 45.4 mg/L [static]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	**IATA**	**IMDG**	**US DOT**	**European ADR**	**Canadian TDG**
14.1	**UN/ID Number**	1824	1824	1824	1824	1824
14.2	**Shipping Name**	Sodium hydroxide solution				
14.3	**Hazard Class**	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	**Packing Group**	II	II	II	II	II
	Special Provisions	A3	None	N34	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable

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Section 14 Transport Information (Continued)

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5	**Environmental Hazards**					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313
No ingredients listed.

CERCLA RG's, 40 CFR 302.4
Potassium Cyanide is listed.
Sodium Hydroxide is listed.

California Proposition 65
Potassium Cyanide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Massachusetts MSL
Potassium Cyanide is listed.
Sodium Hydroxide is listed.

New Jersey Dept. of Health RTK List

Potassium Cyanide is listed.
Sodium Hydroxide is listed.

Pennsylvania RTK
Potassium Cyanide is listed.
Sodium Hydroxide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R36/38 Irritating to eyes and skin.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37/39 Wear suitable gloves and eye/face protection.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1824

Ingredients on Ingredient Disclosure List

Sodium Hydroxide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive

R 35 Causes severe burns.

Eye Dam. 1 - Eye Damage Category 1

Skin Corr. 1A - Skin Corrosion Category 1A

H314 - Causes severe skin burns and eye damage.

H318 - Causes serious eye damage.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

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Section 16 Other Information (Continued)

ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33000-75 Rev. AG
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Reducing Reagent (Compartment R1e)

Part Number Component of P/N 33000

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Slight vinegar odor

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

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Global SDS – English

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight vinegar odor	**Organic**	Not determined
pH	3.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical Stability	The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

No information available.

Microtox

No information available.

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Section 12 Ecological Information (Continued)

	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
CERCLA RG's, 40 CFR 302.4	Acetic Acid is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Acetic Acid is listed.
New Jersey Dept. of Health RTK List	
	Acetic Acid is listed.
Pennsylvania RTK	Acetic Acid is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetic Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated to GHS.	
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances	

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Section 16 Other Information (Continued)

SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

1 Identification

· **Product Identifier**
· **Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials**
· **Catalog Number:** 442265
· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture** In-vitro Diagnostics

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152
Telephone: (410) 771 - 0100 or (800) 638 – 8663
Email Address: Technical_Services@bd.com
· **Information Department:** Technical Service
· **Emergency telephone number:**
In case of a chemical emergency, spill, fire, exposure, or accident, contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 67/548/EEC and 1999/45/EC.
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **NFPA ratings (scale 0-4)**

Health = 0
Flammability = 0
Reactivity = 0

· **HMIS ratings (scale 0-4)**

Health = 0
Flammability = 0
Reactivity = 0

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 1)

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixture**
· **Description:** Mixture consisting of the following components.

· **Dangerous Components:** Void
· **Additional information** Risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Seek medical treatment in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing** If symptoms persist consult doctor.
· **Information for doctor** Show this product label or this SDS.
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture**
No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Wipe up with damp sponge or mop.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 2)

· **Methods and material for containment and cleaning up:** No special measures required.
· **Reference to other sections** No dangerous substances are released.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:**
No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:**
Store away from oxidizing agents.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:**
No further data; see Section 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal Protective Equipment**
· **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.
· **Protection of hands:**

Chemical resistant gloves (i.e. nitrile, or equivalent).

· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing (lab coat).

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 3)

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
Form: Liquid
Color: Light yellow
· **Odor:** Sulphurous

· **Change in condition**
Melting point/Melting range: Not determined
Boiling point/Boiling range: Not determined

· **Flash point:** Not applicable

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with**
Water: Soluble
· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritating effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to OSHA classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 4)

This product or product container contains dry natural rubber latex.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Ecotoxical effects:**
· **Other information:**
The ecological effects have not been thoroughly investigated, but currently none have been identified.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with solid waste.
Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.
This product is not considered a RCRA hazardous waste.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to state and federal regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 5)

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	If "void" appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.
· **UN "Model Regulation":**	-

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

7732-18-5	water
8013-01-2	yeast extract
50-99-7	dextrose
113-24-6	sodium pyruvate
73049-73-7	meat peptone
52993-95-0	SPS

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 6)

68-04-2	Sodium citrate
16009-13-5	hemin
58-27-5	menadione

· **California Proposition 65 - Chemicals known to cause cancer**
None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· **Contact:** Technical Service Representative
· **Date of preparation / last revision** 04/06/2015 / -
· **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances

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Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 04/06/2015 Reviewed On: 04/06/2015

Product Name: BACTEC Lytic/10 Anaerobic/F Culture Vials

(Contd. of page 7)

CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

1 Identification

· **Product Identifier**
· **Product Name: BACTEC Plus Aerobic/F Culture Vials**
· **Catalog Number:** 442192
· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture** In-vitro Diagnostics

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152
Telephone: (410) 771 - 0100 or (800) 638 – 8663
Email Address: Technical_Services@bd.com
· **Information Department:** Technical Service
· **Emergency telephone number:**
In case of a chemical emergency, spill, fire, exposure, or accident, contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 67/548/EEC and 1999/45/EC.
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **NFPA ratings (scale 0-4)**

Health = 0
Flammability = 0
Reactivity = 0

· **HMIS ratings (scale 0-4)**

Health = 0
Flammability = 0
Reactivity = 0

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

Product Name: BACTEC Plus Aerobic/F Culture Vials

(Contd. of page 1)

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixture**
· **Description:** Mixture consisting of the following components.

· **Dangerous Components:** Void
· **Additional information** Risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Seek medical treatment in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing** If symptoms persist consult doctor.
· **Information for doctor** Show this product label or this SDS.
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture**
No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** No special measures required.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

Product Name: BACTEC Plus Aerobic/F Culture Vials

(Contd. of page 2)

· **Methods and material for containment and cleaning up:** No special measures required.
· **Reference to other sections** No dangerous substances are released.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:**
No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** 2 - 25°C
· **Information about storage in one common storage facility:**
Store away from oxidizing agents.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:**
No further data; see Section 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal Protective Equipment**
· **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.
· **Protection of hands:**

Chemical resistant gloves (i.e. nitrile, or equivalent).

· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing (lab coat).

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

Product Name: BACTEC Plus Aerobic/F Culture Vials

(Contd. of page 3)

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Gold Amber
· **Odor:**	Sulphurous
· **pH-value:**	7.3 +/- 0.2
· **Change in condition**	
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with**	
Water:	Soluble
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritating effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

Product Name: BACTEC Plus Aerobic/F Culture Vials

(Contd. of page 4)

· **Additional toxicological information:**
The product is not subject to OSHA classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with solid waste.
Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.
This product is not considered a RCRA hazardous waste.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to state and federal regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

Product Name: BACTEC Plus Aerobic/F Culture Vials

(Contd. of page 5)

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	If "void" appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.
· **UN "Model Regulation":**	-

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 03/11/2015 Reviewed On: 08/19/2014

Product Name: BACTEC Plus Aerobic/F Culture Vials

(Contd. of page 6)

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· **Date of preparation / last revision** 03/11/2015 / -
· **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)

SAFETY DATA SHEET (SDS)

SECTION I - IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND THE COMPANY

PRODUCT NAME:	**Bar Keepers Friend Cleanser & Polish**
RELEVANT IDENTIFIED USES OF THE MIXTURE AND USES ADVISED AGAINST:	Relevant identified uses: Cleans and/or polishes most hard, nonporous surfaces. Do not use on cast iron, granite, marble, wood, fabric, leather, painted surfaces, mirrors, gold, or silver (sterling silver is OK). Do not use where rinsing thoroughly is difficult, or impossible.
MANUFACTURER:	SerVaas Laboratories, Inc 5240 Walt Place Indianapolis, IN 46254 USA
CALL FOR PRODUCT TECHNICAL INFORMATION:	1-800-433-5818 (for USA callers) 1-317-636-7760 (for non-USA callers) www.barkeepersfriend.com
EMERGENCY TELEPHONE NUMBER(CHEMTREC):	1-800-424-9300

SECTION 2 - HAZARDS IDENTIFICATION

CLASSIFICATION OF THE MIXTURE:	Skin irritation 3 - H316 Eye irritation 2A - H319
LABEL ELEMENTS:	
SIGNAL WORD:	Warning
HAZARD PICTOGRAM:	
HAZARD STATEMENTS:	H316 Causes mild skin irritation H319 - Causes serious eye irritation
PREVENTION:	P264 Wash hands thoroughly after handling P280 Wear eye protection / face protection
RESPONSE:	P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice / attention. If medical advice is needed, have container at hand. P332+P313 If skin irritation occurs, get medical attention. If medical advice is needed, have container in hand.

SECTION 3 - COMPOSITION / INFORMATION ON THE INGREDIENTS

INGREDIENT	% By Weight	CAS Reg. No.
FELDSPAR*	Confidential	68476-25-5
LINEAR SODIUM DODECYL BENZENE SULFONATE (DDBSA)	Confidential	69669-44-9
OXALIC ACID	7.5 - 9.5	144-62-7

*not regulated as hazardous materials

SECTION 4 - FIRST AID MEASURES

IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention. If medical advice is needed, have container at hand.
IF INGESTED:	Drink milk or water and call a doctor. Do not induce vomiting. Get medical advice / attention. If medical advice is needed, have container at hand.
IF ON SKIN:	Wash with soap and water. If skin irritation occurs, get medical attention. If medical advice is needed, have container in hand.

SECTION 5 - FIREFIGHTING MEASURES

Not a fire hazard. Use extinguishing media appropriate for surrounding fire.

SPECIAL FIREFIGHTING INSTRUCTIONS:	Wear NIOSH approved self-contained breathing apparatus and protective clothing appropriate for a chemical fire. Cool fire-exposed containers with water spray. Oxalic acid may decompose to carbon monoxide (CO) and formic acid (HCOOH) in fire conditions.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:	For a small spill, wipe up with a mop, paper towels, or cloths. For large spills, use an absorbent such as kitty litter to contain spills. Carefully sweep up, raising a minimum amount of dust, and discard into a household waste container for disposal.
WASTE DISPOSAL METHOD:	Dispose according to the local, state, or federal regulations. Use baking soda to neutralize acid. Wear protective equipment as needed (see section 8).

SECTION 7 - HANDLING AND STORAGE

CONDITIONS FOR SAFE STORAGE:	Keep out of reach of children and domestic animals. Store in a dry place. Keep FROM FREEZING. DO NOT STORE WHERE TEMPERATURE MAY EXCEED 140° F.
CONDITIONS FOR SAFE USE:	Follow use directions on the label. Apply a small amount onto a wet surface or a damp cloth or sponge, then rub gently. Do not mix with other chemicals including bleach or ammonia. Wash hands after use. For prolonged use or sensitive skin, wear waterproof gloves. Respiratory protection is not normally required except as described for firefighting, or if the product is mixed with bleach or ammonia.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

PRIMARY ROUTES OF EXPOSURE:	Dermal contact, hand-to-eye contact. In case of eye contact, see Section 4, First Aid.
ACCIDENTAL OR DELIBERATE INGESTION:	Bar Keepers Friend Cleanser & Polish is of minimal oral toxicity. For ingestion of a large quantity, see Section 4: First Aid.
INDIVIDUAL PROTECTION MEASURES:	Prolonged contact may product dry skin or irritation in some individuals. For prolonged contact or sensitive skin, wear protective gloves (e.g. those meant for household cleaning.)
EXPOSURE LIMITS:	Oxalic acid: ACGIH TLV/ OSHA PEL/ NIOSH REL 1 mg/M3 (TWA) 2 (STEL).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	solid (powder)	COLOR:	white
ODOR:	negligible	pH:	1.5 to 2.5(depending on typical dilution)
FREEZING:	NA	BOILING POINT:	NA
FLASH POINT:	not flammable	EVAPORATION RATE:	NA
SPECIFIC GRAVITY:	0.85 - 0.95	SOLUBILITY:	Oxalic acid and surfactant are soluble in water.

SECTION 10 - STABILITY AND REACTIVITY

STABILITY:	Stable
REACTIVITY:	Incompatible with chlorine bleach, ammonia, and alkaline products.
HAZARDOUS DECOMPOSITION PRODUCTS:	Oxalic acid may decompose to carbon monoxide (CO) and formic acid (HCOOH) in fire conditions.

SECTION 11 - TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

OXALIC ACID:	Oral LD50 >7500 mg/kg (rat)
	Dermal LD50 not determinable
	Eye irritant
	Slight skin irritant
	Inhalation LD50 not determined
	Non sensitizer
DDBSA	Moderate skin and eye irritant

SECTION 12 - ECOLOGICAL INFORMATION

Bar Keepers Friend Cleanser & Polish is of minimal risk to terrestrial wildlife.

Oxalic acid and DDBSA are water soluble. Dissolution of these substances into bodies of water may cause short-term risk to fish and other aquatic organisms. Dissipation in the environment is rapid.

In case of spill, prevent runoff into bodies of water. Clean up spills as described in Section 6.

SECTION 13 - DISPOSAL CONSIDERATIONS

Bar Keepers Friend Cleanser & Polish may be disposed of in household garbage.

SECTION 14 - TRANSPORT INFORMATION

NOT REGULATED BY DOT.

DOT TRANSPORTATION NUMBER:	Not applicable
PACKING GROUP:	Not applicable
MARITIME INFORMATION:	Not applicable
HAZARDOUS SUBSTANCES REPORT QUANTITY:	Not applicable
TDG CLASSIFICATION:	Consumer Commodity-Transborder Consignment
ADR CLASSIFICATION:	Not applicable
IMDG CLASSIFICATION:	Not regulated
IATA CLASSIFICATION:	Does not qualify in manufactured case lot size

SECTION 15 - REGULATORY INFORMATION

U.S. FEDERAL AND STATE REGULATIONS:	SARA Title III Section 313 Toxic Chemical Notification &
RELEASE REPORTING:	None
OTHER CLASSIFICATION:	Not controlled under WHMIS (Canada)

SECTION 16 - OTHER INFORMATION

NFPA	Health Hazards: 2	Flammability: 0	Instability: 0	Special: N/A
HMIS	Health Hazards: 2	Flammability: 0	Physical Hazards: 0	

Disclaimer: The information presented herein is based on available data from reliable sources and is correct to the best of SerVaas Laboratories, Inc. knowledge. SerVaas Laboratories, Inc. makes no warranty, express nor implied, regarding the accuracy of the data or the results obtained from the use of this product. The user is solely responsible for determining the suitability of any material or product for a specific purpose and for adopting any appropriate safety precautions. SerVaas Laboratories, Inc. disclaims all liability for injury or damage stemming from any improper use of the material or product described herein.

Revision Date: June 12, 2015 Supersedes document dated: 5/15/2015

Prepared by: P. SerVaas, SerVaas Laboratories, Inc.

SAFETY DATA SHEET

1. Identification

Product identifier	**BD Vacutainer® Buffered Sodium Citrate Collection Tubes**
Other means of identification	
Product code	368932, 369704, 369714, 368026, 366351, 366392, 366393, 366394, 366395, 366415, 367716
Recommended use	For blood collection and analysis.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company name	BD Diagnostics, PreAnalytical Systems
Address	1 Becton Drive Franklin Lakes, NJ 07417-1885
Telephone	800-631-0174
Contact person	Technical Services
Emergency telephone	Chemtrec US 1-800-424-9300 EU 703-527-3887
E-mail	pas_tech_services@bd.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	This material is not considered hazardous by the OSHA Hazard Communication Standard, OSHA 29 CFR 1910.1200.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

4. First-aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Flush eyes with water as a precaution. If irritation occurs, get medical assistance.
Ingestion	Rinse mouth. Get medical attention if any discomfort occurs.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.

General information	No specific first aid measures noted.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases may be formed.
Special protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid contact with eyes and prolonged skin contact. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	Wipe up spilled material and place in a suitable container for disposal. Following product recovery, flush area with water. For waste disposal, see Section 13 of the SDS.
Environmental precautions	Environmental manager must be informed of all major spillages.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes and prolonged skin contact. Observe good laboratory hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in a cool, dry, well-ventilated place. Keep container closed. Store away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Toluene (CAS 108-88-3)	Ceiling	300 ppm
	TWA	200 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Toluene (CAS 108-88-3)	TWA	20 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Toluene (CAS 108-88-3)	STEL	560 mg/m3
		150 ppm
	TWA	375 mg/m3
		100 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Toluene (CAS 108-88-3)	0.3 mg/g	o-Cresol, with hydrolysis	Creatinine in urine	*
	0.03 mg/l	Toluene	Urine	*
	0.02 mg/l	Toluene	Blood	*

* - For sampling details, please see the source document.

Exposure guidelines	No exposure limits noted for ingredient(s).
Appropriate engineering controls	No particular ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection	Risk of contact: Wear approved safety goggles.
Skin protection	
Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier.
Skin protection	
Other	No protection is ordinarily required under normal conditions of use.
Respiratory protection	Under normal conditions, respirator is not normally required.
Thermal hazards	None.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.
Color	Colorless.
Odor	Odorless.
Odor threshold	Not applicable.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not applicable.
Flammability limit - upper (%)	Not applicable.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Completely soluble in water.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.

Hazardous decomposition products	None expected under normal conditions of use.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged contact may cause dryness of the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization	Based on available data, the classification criteria are not met.
Skin sensitization	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity	Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.
Chronic effects	No specific chronic health impact noted.
Further information	No additional adverse health effects noted.

12. Ecological information

Ecotoxicity	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	This product is water soluble and may disperse in soil.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Do not discharge into drains, water courses or onto the ground.
Hazardous waste code	Not regulated.
Waste from residues / unused products	Dispose of waste and residues in accordance with local authority requirements.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Toluene (CAS 108-88-3)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 17-May-2016

Revision date -

Version # 01

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings

References
ACGIH: American Conference of Governmental and Industrial Hygienists.
US. IARC Monographs on Occupational Exposures to Chemical Agents
IARC Monographs. Overall Evaluation of Carcinogenicity
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices

Disclaimer To the best of our knowledge, the information contained herein is accurate. However, neither BD nor any of its subsidiaries assumes any liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing Date: 2005-Jan-28 *Printing Date: Reviewed on*

Product Name: *BD Vacutainer® Brand Tube with ACD Solution A or B*

1 Identification of substance:

- ***Product Details:***
  MSDS Number:VS60316-03
  Issue Date: January 24, 2005
  Supersedes:VS60316-02
  ECO No.: ECO24505
- ***Product Name:*** *BD Vacutainer® Brand Tube with ACD Solution A or B*
- ***Catalog Numbers:*** *364012, 364606, 364816, 367756, 368030 Discontinued: 361014, 364001, 364003, 364011*
- ***Manufacturer/Supplier:***
  BD Diagnostics, Preanalytical Systems
  1 Becton Drive
  Franklin Lakes, NJ, 07417-1885
- ***Information Department:***
  BD Diagnostics, Preanalytical Systems Technical Service, (800) 631-0174
- ***Emergency Information:***
  In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, Preanalytical Systems, at (308) 423-0300, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- ***Description:***
  Chemical name: *Sodium citrate, Dextrose, and Citric acid monohydrate*
  Synonyms*: Sodium citrate: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, trisodium salt; Lithium citrate hydrate; Trisodium citrate*
  Dextrose: Syrups, hydrolyzed starch, dehydrated
  Citric acid monohydrate: Citric acid hydrate; 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate
- ***CAS No.:*** *Sodium citrate: 68-04-2*
  Dextrose: 68131-37-3
  Citric acid monohydrate: 5949-29-1
- ***Quantity of substances:*** *Sodium citrate: 1.6 – 11.2 mg (0.4 – 0.75%)*
  Dextrose: 1.1 – 6.6 mg (0.3 – 0.4%)
  Citric acid monohydrate: 0.4 – 2.5 mg (0.1 – 0.17%)
- ***Exposure limits:*** *Not established*

3 Hazards identification:

- ***Hazard description:***

  EU: *This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by European Directive 91/155/EEC, and 93/112/EC.*

  U.S.: *May cause eye and skin irritation. Inhalation of large amounts of dust may be irritating to the respiratory tract. May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing.*
  Primary route of entry: skin, eyes, inhalation and ingestion

- ***Classification system:*** *The classification is according to the latest editions of the EU- list, and extended by company and literature data.*
- ***Acute Exposure Effects:***
  Eyes: May cause eye irritation.
  Skin: May cause skin irritation.
  Inhalation: Inhalation of large amounts of dust may be irritating to the upper respiratory tract.
  Ingestion: May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing..
- ***Repeated Exposure Effects:***
  Eyes: None identified.
  Skin: None identified.
  Inhalation: None identified.
  Ingestion: None identified.
- ***Medical Conditions Which Might be Aggravated:*** *None identified.*
- ***NFPA ratings (scale 0-4):***

Health =1
Fire = 0
Reactivity = 0
Specific Hazard = 0

- ***HMIS ratings (scale 0-4):***

Health =1
Flammability = 0
Reactivity = 0
Special = 0

4 First aid measures:

General information: *No special measures required*
After inhalation: *Remove victim to fresh air. Seek immediate medical attention if breathing is difficult.*
After skin contact: *Wash affected area thoroughly with soap and water. Seek medical attention if irritation develops.*
After eye contact: *Rinse opened eye for 15 minutes under running water. Seek medical attention if irritation develops.*
After Swallowing: *Give 2 to 4 glasses of water to dilute. Seek immediate medical attention.*
Information for doctor: *Show this label*

5 Fire fighting measures:

- ***Suitable extinguishing agents:*** *Water spray, dry chemical, carbon dioxide, or alcohol foam.*
- ***Protective equipment:*** *Wear self-contained NIOSH approved breathing apparatus operated in positive pressure mode, and full protective clothing to prevent contact with skin and eyes. Keep containers cool by spraying with water.*

6 Accidental release measures:

- **Person-related safety precautions:** Avoid overexposure. Wear protective equipment, including NIOSH approved respirator.
- **Measures for environmental protection:** Not applicable
- **Measures for cleaning/collecting:** Do not dry-sweep. Wet down to minimize airborne dust. Place in an appropriate disposal container. Flush area with water.
- **Additional information:** None

7 Handling and storage:

- **Handling:**

  Information for safe handling: Do not breathe dust. Avoid dust generation or accumulation. Use adequate ventilation and dust collection.
  Information about protection against explosions and fires: Not applicable.
- **Storage:**

  Requirements to be met by storerooms and receptacles: Use suitable containers. Keep tightly closed when not in use. Store in a cool, dry, well-ventilated area.

  Information about storage in one common storage facility: Store away from incompatible materials, such as strong bases and strong oxidizing agents.

  Further information about storage conditions: None

8 Exposure controls and personal protection:

- **Additional information about design of technical systems:** Use sufficient local or general exhaust.
- **Components with limit values that require monitoring at the workplace:**
  Exposure limits: None established
- **Additional information:** Not applicable
- **Personal Protective Equipment:**

  General protective hygiene measures: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation. Use with adequate ventilation. Provide eye bath and safety shower.
  Breathing equipment: NIOSH-approved respirator

  Protection of hands: Wear appropriate protective gloves to prevent skin exposure.
  Eye protection: Use chemical safety goggles
  Body protection: Wear appropriate protective clothing to prevent skin exposure.

09 Physical and chemical properties:

- **General Information:**

  Form: Powder

Color: *Colorless*
Odor: *Odorless*

- ***Change in condition:***
  Melting point/Melting range: *Not determined*
  Boiling point/Boiling range: *Not determined*
- ***Flash point:*** *Not applicable*
- ***Flammability (solid, gaseous):*** *Not applicable*
- ***Danger of explosion:*** *Under proper handling conditions, product does not present an explosion hazard.*
- ***Vapor pressure:*** *Not applicable*
- ***Density:*** *Not determined*
- ***Solubility in/Miscibility w/H_2O:*** *Not determined*
- ***pH-value:*** *Not applicable*
  Organic solvents: *Not applicable*
- ***Solids content:*** *Not available*

10 Stability and reactivity:

- ***Thermal decomposition / conditions to be avoided****: None identified*
- ***Materials to be avoided****: Strong bases and strong oxidizing agents*
- ***Dangerous reactions****: Stable; none known*
- ***Dangerous products of decomposition****: Oxides of carbon. Acid smoke and fumes will be emitted when heated.*

11 Toxicological information:

- ***Acute toxicity****:*
  Eye: May cause eye irritation.
  Skin: May cause skin irritation.
  Inhalation: Inhalation of large amounts of dust may be irritating to the upper respiratory tract.
  Ingestion: May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing..
- ***Primary irritant effect:***
  On the skin: Not established
  On the eye: Not established
- ***Sensitization****: Not established*
- ***Additional toxicological information****:*
  Chronic: *Not established*
  Carcinogenicity: *Does not contain more than 0.1% by weight of a material listed as a potential carcinogen by NTP, IARC, or OSHA.*

12 Ecological information:

- **Ecotoxicological effects:** No data is available on the adverse effects of this material on the environment. Neither COD nor BOD data are available.
- **Other information:** Not applicable
- **General notes:** Not applicable

13 Disposal considerations:

- **Product:**
  Recommendation
  Disposal should be done in accordance with local, state and federal regulations.
  Disposal must be made according to the regulations found in 40 CFR 261.
  This product is not a RCRA hazardous waste.
- **Uncleaned packagings:**
  Recommendation
  Disposal should be done in accordance with local, state and federal regulations.
  Recommended cleansing agent
  Water, if necessary with cleansing agents

14 Transport information:

- **DOT regulations:** Not regulated
- **Land transport ADR/RID (cross-border):** Not regulated
- **Maritime transport IMDG:** Not regulated
- **Air transport ICAO-TI and IATA-DGR:** Not regulated

15 Regulations:

- **SARA Section 355 (extremely hazardous substances):** Substances not listed
- **SARA Section 302 (extremely hazardous substances):** Substances not listed
- **SARA Section 304 (Reportable Quantity (RQ) under CERCLA):** None
- **Section 313 (specific toxic chemical listings):** Substances not listed
- **TSCA (Toxic Substances Control Act) Inventory:** Substances listed
- **California Proposition 65 – Chemicals Known to Cause Cancer**: Substances not listed
  California Proposition 65 – Chemicals Known to Cause Reproductive Toxicity: Substances not listed
- **SARA Section 311/312 (Hazard notification categories under SARA Title III):** None
- **Hazardous chemical(s) under OSHA Hazard Communication Standard (29 CFR 1910.1200):** None

- ***Carncinogenicity categories***
  IARC (International Agency for Research on Cancer): *Substances not listed*
  NTP (National Toxicology Program): *Substance not listed*
  TLV (Threshold Limit Value established by ACGIH): *Substances not listed*
  MAK (German Maximum Workplace Concentration): *Substances not listed*
- ***Product related hazard information:*** *None*
- ***National regulations:*** *Not applicable*
- ***Water hazard class:*** *Not applicable*

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither BD or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

- ***Department issuing MSDS:*** *Regulatory Affairs*

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing Date: 2005-Jan-28 *Printing Date: Reviewed on*

Product Name: *BD Vacutainer® Brand Tube with ACD Solution A or B*

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- ***Emergency Information:***
  In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, Preanalytical Systems, at (308) 423-0300, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- ***Description:***
  Chemical name: *Sodium citrate, Dextrose, and Citric acid monohydrate*
  Synonyms*: Sodium citrate: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, trisodium salt; Lithium citrate hydrate; Trisodium citrate*
  Dextrose: Syrups, hydrolyzed starch, dehydrated
  Citric acid monohydrate: Citric acid hydrate; 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate
- ***CAS No.:*** *Sodium citrate: 68-04-2*
  Dextrose: 68131-37-3
  Citric acid monohydrate: 5949-29-1
- ***Quantity of substances:*** *Sodium citrate: 1.6 – 11.2 mg (0.4 – 0.75%)*
  Dextrose: 1.1 – 6.6 mg (0.3 – 0.4%)
  Citric acid monohydrate: 0.4 – 2.5 mg (0.1 – 0.17%)
- ***Exposure limits:*** *Not established*

3 Hazards identification:

- ***Hazard description:***

  EU: *This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by European Directive 91/155/EEC, and 93/112/EC.*

  U.S.: *May cause eye and skin irritation. Inhalation of large amounts of dust may be irritating to the respiratory tract. May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing.*
  Primary route of entry: skin, eyes, inhalation and ingestion

- ***Classification system:*** *The classification is according to the latest editions of the EU- list, and extended by company and literature data.*
- ***Acute Exposure Effects:***
  Eyes: May cause eye irritation.
  Skin: May cause skin irritation.
  Inhalation: Inhalation of large amounts of dust may be irritating to the upper respiratory tract.
  Ingestion: May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing..
- ***Repeated Exposure Effects:***
  Eyes: None identified.
  Skin: None identified.
  Inhalation: None identified.
  Ingestion: None identified.
- ***Medical Conditions Which Might be Aggravated:*** *None identified.*
- ***NFPA ratings (scale 0-4):***

Health =1
Fire = 0
Reactivity = 0
Specific Hazard = 0

- ***HMIS ratings (scale 0-4):***

Health =1
Flammability = 0
Reactivity = 0
Special = 0

4 First aid measures:

General information: *No special measures required*
After inhalation: *Remove victim to fresh air. Seek immediate medical attention if breathing is difficult.*
After skin contact: *Wash affected area thoroughly with soap and water. Seek medical attention if irritation develops.*
After eye contact: *Rinse opened eye for 15 minutes under running water. Seek medical attention if irritation develops.*
After Swallowing: *Give 2 to 4 glasses of water to dilute. Seek immediate medical attention.*
Information for doctor: *Show this label*

5 Fire fighting measures:

- ***Suitable extinguishing agents:*** *Water spray, dry chemical, carbon dioxide, or alcohol foam.*
- ***Protective equipment:*** *Wear self-contained NIOSH approved breathing apparatus operated in positive pressure mode, and full protective clothing to prevent contact with skin and eyes. Keep containers cool by spraying with water.*

6 Accidental release measures:

- **Person-related safety precautions:** Avoid overexposure. Wear protective equipment, including NIOSH approved respirator.
- **Measures for environmental protection:** Not applicable
- **Measures for cleaning/collecting:** Do not dry-sweep. Wet down to minimize airborne dust. Place in an appropriate disposal container. Flush area with water.
- **Additional information:** None

7 Handling and storage:

- **Handling:**

  Information for safe handling: Do not breathe dust. Avoid dust generation or accumulation. Use adequate ventilation and dust collection.
  Information about protection against explosions and fires: Not applicable.
- **Storage:**

  Requirements to be met by storerooms and receptacles: Use suitable containers. Keep tightly closed when not in use. Store in a cool, dry, well-ventilated area.

  Information about storage in one common storage facility: Store away from incompatible materials, such as strong bases and strong oxidizing agents.

  Further information about storage conditions: None

8 Exposure controls and personal protection:

- **Additional information about design of technical systems:** Use sufficient local or general exhaust.
- **Components with limit values that require monitoring at the workplace:**
  Exposure limits: None established
- **Additional information:** Not applicable
- **Personal Protective Equipment:**

  General protective hygiene measures: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation. Use with adequate ventilation. Provide eye bath and safety shower.
  Breathing equipment: NIOSH-approved respirator

  Protection of hands: Wear appropriate protective gloves to prevent skin exposure.
  Eye protection: Use chemical safety goggles
  Body protection: Wear appropriate protective clothing to prevent skin exposure.

09 Physical and chemical properties:

- **General Information:**

  Form: Powder

Color: *Colorless*
Odor: *Odorless*

- ***Change in condition:***
  Melting point/Melting range: *Not determined*
  Boiling point/Boiling range: *Not determined*
- ***Flash point:*** *Not applicable*
- ***Flammability (solid, gaseous):*** *Not applicable*
- ***Danger of explosion:*** *Under proper handling conditions, product does not present an explosion hazard.*
- ***Vapor pressure:*** *Not applicable*
- ***Density:*** *Not determined*
- ***Solubility in/Miscibility w/H_2O:*** *Not determined*
- ***pH-value:*** *Not applicable*
  Organic solvents: *Not applicable*
- ***Solids content:*** *Not available*

10 Stability and reactivity:

- ***Thermal decomposition / conditions to be avoided****: None identified*
- ***Materials to be avoided****: Strong bases and strong oxidizing agents*
- ***Dangerous reactions****: Stable; none known*
- ***Dangerous products of decomposition****: Oxides of carbon. Acid smoke and fumes will be emitted when heated.*

11 Toxicological information:

- ***Acute toxicity****:*
  Eye: May cause eye irritation.
  Skin: May cause skin irritation.
  Inhalation: Inhalation of large amounts of dust may be irritating to the upper respiratory tract.
  Ingestion: May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing..
- ***Primary irritant effect:***
  On the skin: Not established
  On the eye: Not established
- ***Sensitization****: Not established*
- ***Additional toxicological information****:*
  Chronic: *Not established*
  Carcinogenicity: *Does not contain more than 0.1% by weight of a material listed as a potential carcinogen by NTP, IARC, or OSHA.*

12 Ecological information:

- **Ecotoxicological effects:** No data is available on the adverse effects of this material on the environment. Neither COD nor BOD data are available.
- **Other information:** Not applicable
- **General notes:** Not applicable

13 Disposal considerations:

- **Product:**
  Recommendation
  Disposal should be done in accordance with local, state and federal regulations.
  Disposal must be made according to the regulations found in 40 CFR 261.
  This product is not a RCRA hazardous waste.
- **Uncleaned packagings:**
  Recommendation
  Disposal should be done in accordance with local, state and federal regulations.
  Recommended cleansing agent
  Water, if necessary with cleansing agents

14 Transport information:

- **DOT regulations:** Not regulated
- **Land transport ADR/RID (cross-border):** Not regulated
- **Maritime transport IMDG:** Not regulated
- **Air transport ICAO-TI and IATA-DGR:** Not regulated

15 Regulations:

- **SARA Section 355 (extremely hazardous substances):** Substances not listed
- **SARA Section 302 (extremely hazardous substances):** Substances not listed
- **SARA Section 304 (Reportable Quantity (RQ) under CERCLA):** None
- **Section 313 (specific toxic chemical listings):** Substances not listed
- **TSCA (Toxic Substances Control Act) Inventory:** Substances listed
- **California Proposition 65 – Chemicals Known to Cause Cancer**: Substances not listed
  California Proposition 65 – Chemicals Known to Cause Reproductive Toxicity: Substances not listed
- **SARA Section 311/312 (Hazard notification categories under SARA Title III):** None
- **Hazardous chemical(s) under OSHA Hazard Communication Standard (29 CFR 1910.1200):** None

- ***Carncinogenicity categories***
  IARC (International Agency for Research on Cancer): *Substances not listed*
  NTP (National Toxicology Program): *Substance not listed*
  TLV (Threshold Limit Value established by ACGIH): *Substances not listed*
  MAK (German Maximum Workplace Concentration): *Substances not listed*
- ***Product related hazard information:*** *None*
- ***National regulations:*** *Not applicable*
- ***Water hazard class:*** *Not applicable*

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither BD or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

- ***Department issuing MSDS:*** *Regulatory Affairs*

Version: 18.1
Last revised date: 10/15/2018

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SAFETY DATA SHEET

1. Identification

Product identifier

Product No.:	Product name:	Common name(s), synonym(s)
365974	TUBE MICRO W/MICROGARD EDTA LAV	BD Microtainer® K2EDTA Blood CollectionTube w/Microgard

Other means of identification

SDS number: 088100181141

Recommended use and restriction on use

Recommended use: Scientific and industrial laboratory use. For In Vitro Diagnostic Use.
Restrictions on use: For External Use Only

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name:	BD Diagnostics, Preanalytical Systems
Address:	1 Becton Drive 07417 Franklin Lakes, NJ USA
Telephone:	1 800 631 0174
Fax:	1 201 847 4866
Contact Person:	Technical Services
E-mail:	pas_tech_services@bd.com

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Health Hazards

Acute toxicity (Inhalation - dust and mist)	Category 4

Label Elements

Hazard Symbol:

Signal Word: Warning

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Hazard Statement: H332: Harmful if inhaled.

Precautionary Statements

Prevention: P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
P271: Use only outdoors or in a well-ventilated area.

Response: P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312: Call a POISON CENTER/doctor if you feel unwell.

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

Substances

Chemical Identity	Common name and synonyms	CAS number	Content in percent (%)*
Dipotassium EDTA		25102-12-9	50 - <100%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

General information: No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, GET MEDICAL ATTENTION PROMPTLY!

Ingestion: Seek medical advice. Due to the small packaging the risk of ingestion is minimal.

Inhalation: Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Move into fresh air and keep at rest. Get medical attention if symptoms persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin Contact: Wash skin with soap and water. Due to the small packaging the risk of skin contact is minimal.

Eye contact: If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor. Due to the small packaging the risk of eye contact is minimal.

Most important symptoms/effects, acute and delayed

Symptoms: No specific symptoms noted.

Hazards: Low hazard for recommended handling by trained personnel.

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Indication of immediate medical attention and special treatment needed

Treatment: Get medical attention if symptoms occur.

5. Fire-fighting measures

General Fire Hazards: No unusual fire or explosion hazards noted.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: None known.

Special protective equipment and precautions for firefighters

Special fire fighting procedures: No unusual fire or explosion hazards noted.

Special protective equipment for fire-fighters: No specific precautions due to the small quantities handled. Use fire-extinguishing media appropriate for surrounding materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid breathing dust/fume/gas/mist/vapors/spray.

Methods and material for containment and cleaning up: Sweep or scoop up and remove.

Environmental Precautions: Avoid release to the environment.

7. Handling and storage

Precautions for safe handling: Wear appropriate personal protective equipment. Observe good laboratory hygiene practices. Low hazard for recommended handling by trained personnel.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place out of direct sunlight. Store in closed original container at temperatures between 4°C and 25°

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8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure limits.

Appropriate Engineering Controls Observe good industrial hygiene practices. Low hazard for recommended handling by trained personnel.

Individual protection measures, such as personal protective equipment

General information: No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals.

Eye/face protection: Avoid contact with eyes and prolonged skin contact. Protective gloves and goggles must be used if there is a risk of direct contact or splash.

Skin Protection

Hand Protection: Use suitable protective gloves if risk of skin contact.

Other: No data available.

Respiratory Protection: Not relevant, due to the form of the product. The risk of inhalation of dust must be minimized as much as possible.

Hygiene measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state:	Crystalline Powder.
Form:	Crystalline Powder.
Color:	White
Odor:	Odorless
Odor threshold:	No data available.
pH:	No data available.
Melting point/freezing point:	The physical-chemical properties of this material have not been fully investigated.
Initial boiling point and boiling range:	The physical-chemical properties of this material have not been fully investigated.
Flash Point:	Not applicable
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.

Upper/lower limit on flammability or explosive limits

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Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Explosive limit - upper (%):	No data available.
Explosive limit - lower (%):	No data available.
Vapor pressure:	The physical-chemical properties of this material have not been fully investigated.
Vapor density:	No data available.
Relative density:	The physical-chemical properties of this material have not been fully investigated.
Solubility(ies)	
Solubility in water:	The physical-chemical properties of this material have not been fully investigated.
Solubility (other):	Not applicable
Partition coefficient (n-octanol/water):	The physical-chemical properties of this material have not been fully investigated.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	Not determined.

10. Stability and reactivity

Reactivity:	Stable under normal temperature conditions and recommended use.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	None under normal conditions.
Conditions to avoid:	None known. None under normal conditions.
Incompatible Materials:	No common materials and contaminants with which the material may reasonably come into contact.
Hazardous Decomposition Products:	Material is stable under normal conditions.

11. Toxicological information

General information:	Under normal conditions of intended use, this material does not pose a risk to health.

Information on likely routes of exposure

Ingestion:	Expected to be a low ingestion hazard.
Inhalation:	Harmful if inhaled. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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Skin Contact: Due to the small packaging the risk of skin contact is minimal.

Eye contact: Due to the small packaging the risk of eye contact is minimal.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion: No specific symptoms noted.

Inhalation: No specific symptoms noted.

Skin Contact: No specific symptoms noted.

Eye contact: No specific symptoms noted.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: No data available.

Dermal
Product: No data available.

Inhalation
Product: ATEmix: 1.5 mg/l

Repeated dose toxicity
Product: No data available.

Skin Corrosion/Irritation
Product: No data available.

Serious Eye Damage/Eye Irritation
Product: No data available.

Respiratory or Skin Sensitization
Product: No data available.

Carcinogenicity
Product: No data available.

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IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro
Product: No data available.

In vivo
Product: No data available.

Reproductive toxicity
Product: No data available.

Specific Target Organ Toxicity - Single Exposure
Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure
Product: No data available.

Aspiration Hazard
Product: No data available.

Other effects: No data available.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish
Product: No data available.

Aquatic Invertebrates
Product: No data available.

Chronic hazards to the aquatic environment:

Fish

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Product: No data available.

Aquatic Invertebrates
Product: No data available.

Toxicity to Aquatic Plants
Product: No data available.

Persistence and Degradability

Biodegradation
Product: No data available.

BOD/COD Ratio
Product: No data available.

Bioaccumulative potential
Bioconcentration Factor (BCF)
Product: No data available.

Partition Coefficient n-octanol / water (log Kow)
Product: Log Kow: The physical-chemical properties of this material have not been fully investigated.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments
Dipotassium EDTA No data available.

Other adverse effects: No data available.

13. Disposal considerations

Disposal instructions: Dispose of waste and residues in accordance with local authority requirements.

Contaminated Packaging: No data available.

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14. Transport information

DOTUN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Label(s):	Not regulated.
Packing Group:	Not regulated.
Marine Pollutant:	Not regulated.
Limited quantity	Not regulated.
Excepted quantity	Not regulated.
Special precautions for user:	Not regulated.

IMDG

UN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
EmS No.:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine Pollutant:	Not regulated.
Special precautions for user:	Not regulated.

IATA

UN Number:	Not regulated.
Proper Shipping Name:	Not regulated.
Transport Hazard Class(es):	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine pollutant:	Not regulated.
Special precautions for user:	Not regulated.

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
None present or none present in regulated quantities.

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CERCLA Hazardous Substance List (40 CFR 302.4):
None present or none present in regulated quantities.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Not listed.

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

SARA 304 Emergency Release Notification
None present or none present in regulated quantities.

SARA 311/312 Hazardous Chemical

Chemical Identity	Threshold Planning Quantity
Dipotassium EDTA	10000 lbs

SARA 313 (TRI Reporting)
None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)
None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):
None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65
No ingredient regulated by CA Prop 65 present.

US. New Jersey Worker and Community Right-to-Know Act
No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List
No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances
No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK
No ingredient regulated by RI Right-to-Know Law present.

16.Other information, including date of preparation or last revision

Issue Date: 10/15/2018

Version #: 18.1

Version: 18.1
Last revised date: 10/15/2018

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Revision Information:

Further Information: No data available.

Disclaimer:

Disclaimer:
The information contained herein has been obtained from various sources and is believed to be correct as of the date issued. However, neither BD nor any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability for a particular use of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. BD provides SDS in electronic form so the information may be more easily accessed. Due to the possibility of errors during transmission, BD makes no representations as to the completeness or accuracy of the information.

Material Safety Data Sheet
acc. to ISO/DIS 11014

Product Name: BD Vacutainer® Brand Tube with Sodium Citrate Buffer Solution

1 Identification of substance:

- **Product Details:**
  MSDS Number:VS60317-11
  Issue Date: September 12, 2013
  Supersedes:VS60317-10
- **Product Name:** BD Vacutainer® Brand Tube with Sodium Citrate Buffer Solution
- **Catalog Numbers:** 363083
- **Manufacturer/Supplier:**
  BD Diagnostics, Preanalytical Systems
  1 Becton Drive
  Franklin Lakes, NJ, 07417-1885
- **Information Department:**
  BD Diagnostics, Preanalytical Systems Technical Service, (800) 631-0174
- **Emergency Information:**
  In case of a chemical emergency, spill, fire, exposure, contact ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- **Description:**
  Chemical name: Sodium citrate
  Synonyms: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, trisodium salt; Lithium citrate hydrate; Trisodium citrate
- **CAS No.:** 68-04-2
- **Quantity of substances:** 6.3 – 39 mg
- **Exposure limits:** Not established

3 Hazards identification:

- **Hazard description:**

  EU: This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by European Directive 91/155/EEC, and 93/112/EC.

  U.S.: May cause eye and skin irritation. Inhalation of large amounts of dust may be irritating to the respiratory tract. May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing.
  Primary route of entry: skin, eyes, inhalation and ingestion
- **Classification system:** The classification is according to the latest editions of the EU- list, and extended by company and literature data.
- **Acute Exposure Effects:**
  Eyes: May cause eye irritation.
  Skin: May cause skin irritation.
  Inhalation: Inhalation of large amounts of dust may be irritating to the upper respiratory tract.
  Ingestion: May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing..
- **Repeated Exposure Effects:**

Product Name: BD Vacutainer® Brand Tube with Sodium Citrate Buffer Solution

Eyes: None identified.

Skin: None identified.

Inhalation: None identified.

Ingestion: None identified.

- ***Medical Conditions Which Might be Aggravated:*** *None identified.*
- ***NFPA ratings (scale 0-4):***

Health =1
Fire = 0
Reactivity = 0
Specific Hazard = 0

- ***HMIS ratings (scale 0-4):***

Health =1
Flammability = 0
Reactivity = 0
Special = 0

4 First aid measures:

General information: *No special measures required*
After inhalation: *Remove victim to fresh air. Seek immediate medical attention if breathing is difficult.*
After skin contact: *Wash affected area thoroughly with soap and water. Seek medical attention if irritation develops.*
After eye contact: *Rinse opened eye for 15 minutes under running water. Seek medical attention if irritation develops.*
After Swallowing: *Give 2 to 4 glasses of water to dilute. Seek immediate medical attention.*
Information for doctor: *Show this label*

5 Fire fighting measures:

- ***Suitable extinguishing agents:*** *Water spray, dry chemical, carbon dioxide, or alcohol foam.*
- ***Protective equipment:*** *Wear self-contained NIOSH approved breathing apparatus operated in positive pressure mode, and full protective clothing to prevent contact with skin and eyes. Keep containers cool by spraying with water.*

Product Name: BD Vacutainer® Brand Tube with Sodium Citrate Buffer Solution

6 Accidental release measures:

- **Person-related safety precautions:** Avoid overexposure. Wear protective equipment, including NIOSH approved respirator.
- **Measures for environmental protection:** Not applicable
- **Measures for cleaning/collecting:** Do not dry-sweep. Wet down to minimize airborne dust. Place in an appropriate disposal container. Flush area with water.
- **Additional information:** None

7 Handling and storage:

- **Handling:**

  Information for safe handling: Do not breathe dust. Avoid dust generation or accumulation. Use adequate ventilation and dust collection.
  Information about protection against explosions and fires: Not applicable.
- **Storage:**

  Requirements to be met by storerooms and receptacles: Use suitable containers. Keep tightly closed when not in use. Store in a cool, dry, well-ventilated area.

  Information about storage in one common storage facility: Store away from incompatible materials, such as strong bases and strong oxidizing agents.

  Further information about storage conditions: None

8 Exposure controls and personal protection:

- **Additional information about design of technical systems:** Use sufficient local or general exhaust.
- **Components with limit values that require monitoring at the workplace:**
  Exposure limits: None established
- **Additional information:** Not applicable
- **Personal Protective Equipment:**

  General protective hygiene measures: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation. Use with adequate ventilation. Provide eye bath and safety shower.
  Breathing equipment: NIOSH-approved respirator

  Protection of hands: Wear appropriate protective gloves to prevent skin exposure.
  Eye protection: Use chemical safety goggles
  Body protection: Wear appropriate protective clothing to prevent skin exposure.

09 Physical and chemical properties:

- **General Information:**

  Form: Powder

Product Name: *BD Vacutainer® Brand Tube with Sodium Citrate Buffer Solution*

Color: *Colorless*
Odor: *Odorless*

- ***Change in condition:***
  Melting point/Melting range: *Not determined*
  Boiling point/Boiling range: *Not determined*
- ***Flash point:*** *Not applicable*
- ***Flammability (solid, gaseous):*** *Not applicable*
- ***Danger of explosion:*** *Under proper handling conditions, product does not present an explosion hazard.*
- ***Vapor pressure:*** *Not applicable*
- ***Density:*** *Not determined*
- ***Solubility in/Miscibility w/H_2O:*** *Not determined*
- ***pH-value:*** *Not applicable*
  Organic solvents: *Not applicable*
- ***Solids content:*** *Not available*

10 Stability and reactivity:

- ***Thermal decomposition / conditions to be avoided****: None identified*
- ***Materials to be avoided****: Strong bases and strong oxidizing agents.*
- ***Dangerous reactions****: Stable; none known.*
- ***Dangerous products of decomposition****: Oxides of carbon. Acid smoke and fumes will be emitted when heated.*

11 Toxicological information:

- ***Acute toxicity****:*
  Eye: May cause eye irritation.
  Skin: May cause skin irritation.
  Inhalation: Inhalation of large amounts of dust may be irritating to the upper respiratory tract.
  Ingestion: May cause nausea and vomiting if ingested in large quantities. May also cause hypernoia and convulsing..
- ***Primary irritant effect:***
  On the skin: Not established
  On the eye: Not established
- ***Sensitization****: Not established*
- ***Additional toxicological information****:*
  Chronic: *Not established*
  Carcinogenicity: *Does not contain more than 0.1% by weight of a material listed as a potential carcinogen by NTP, IARC, or OSHA.*

12 Ecological information:

- ***Ecotoxicological effects:*** *No data is available on the adverse effects of this material on the environment. Neither COD nor BOD data are available.*
- ***Other information:*** *Not applicable*
- ***General notes:*** *Not applicable*

13 Disposal considerations:

- ***Product:***
  Recommendation
  Disposal should be done in accordance with local, state and federal regulations.
  Disposal must be made according to the regulations found in 40 CFR 261.
  This product is not a RCRA hazardous waste.
- ***Uncleaned packagings:***
  Recommendation
  Disposal should be done in accordance with local, state and federal regulations.
  Recommended cleansing agent
  Water, if necessary with cleansing agents

14 Transport information:

- ***DOT regulations:*** *Not regulated*
- ***Land transport ADR/RID (cross-border):*** *Not regulated*
- ***Maritime transport IMDG:*** *Not regulated*
- ***Air transport ICAO-TI and IATA-DGR:*** *Not regulated*

15 Regulations:

- ***SARA Section 355 (extremely hazardous substances):*** *Substance not listed*
- ***SARA Section 302 (extremely hazardous substances):*** *Substance not listed*
- ***SARA Section 304 (Reportable Quantity (RQ) under CERCLA):*** *None*
- ***Section 313 (specific toxic chemical listings):*** *Substance not listed*
- ***TSCA (Toxic Substances Control Act) Inventory:*** *Substance listed*
- ***California Proposition 65 – Chemicals Known to Cause Cancer****: Substance not listed*
  California Proposition 65 – Chemicals Known to Cause Reproductive Toxicity*: Substance not listed*
- ***SARA Section 311/312 (Hazard notification categories under SARA Title III):*** *None*
- ***Hazardous chemical(s) under OSHA Hazard Communication Standard (29 CFR 1910.1200):*** *None*

- ***Carncinogenicity categories***
  IARC (International Agency for Research on Cancer): *Substance not listed*
  NTP (National Toxicology Program): *Substance not listed*
  TLV (Threshold Limit Value established by ACGIH): *Substance not listed*
  MAK (German Maximum Workplace Concentration): *Substance not listed*
- ***Product related hazard information:*** *None*
- ***National regulations:*** *Not applicable*
- ***Water hazard class:*** *Not applicable*

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither BD or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

- ***Department issuing MSDS:*** *Regulatory Affairs*

SAFETY DATA SHEET

1. Identification

Product identifier **BD Vacutainer® C&S Urine Tubes**

Other means of identification

Product code 364953, 364954, 364955, 364958, 364959, 364944, 364951, 364969

Recommended use For urine collection and analysis.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name BD Diagnostics, PreAnalytical Systems

Address 1 Becton Drive
Franklin Lakes, NJ 07417-1885

Telephone 800-631-0174

Contact person Technical Services

Emergency telephone Chemtrec US 1-800-424-9300 EU 703-527-3887

E-mail pas_tech_services@bd.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Serious eye damage/eye irritation	Category 2A
Reproductive toxicity (fertility, the unborn child)	Category 1B

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement Causes serious eye irritation. May damage fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling.

Response If exposed or concerned: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Borax decahydrate	1303-96-4	20-40
Boric acid	11113-50-1	10-30

Composition comments	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. Components not listed are either non-hazardous or are below reportable limits.

4. First-aid measures

Inhalation	No specific precautions due to the small quantities handled. However: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or doctor/physician if you feel unwell.
Skin contact	No specific precautions due to the small quantities handled. However: Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.
Eye contact	No specific precautions due to the small quantities handled. However, rinse with water. Do not rub eye. Make sure to remove any contact lenses from the eyes before rinsing. Get medical attention if irritation develops and persists.
Ingestion	No specific precautions due to the small quantities handled. However: Rinse mouth thoroughly if dust is ingested. Get medical attention if any discomfort occurs.
Most important symptoms/effects, acute and delayed	Under normal conditions of intended use, this material does not pose a risk to health.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials. Containers close to fire should be removed or cooled with water.
General fire hazards	The product itself does not burn.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Provide adequate ventilation. Avoid dust formation. Avoid inhalation of dust and contact with skin and eyes. See Section 8 of the SDS for Personal Protective Equipment. As supplied, the product is expected to pose no immediate health or fire hazard.
Methods and materials for containment and cleaning up	Collect dust using a vacuum cleaner equipped with HEPA filter. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground unless authorized by permit.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Pregnant women should not work with the product, if there is the least risk of exposure. Provide adequate ventilation. Avoid generation and spreading of dust. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Do not taste or swallow. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Keep the workplace clean. Observe good industrial hygiene practices. As supplied, the product is expected to pose no immediate health or fire hazard.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a cool, dry place.

8. Exposure controls/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Borax decahydrate (CAS 1303-96-4)	STEL	6 mg/m3	Inhalable fraction.
	TWA	2 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Borax decahydrate (CAS 1303-96-4)	TWA	5 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear dust goggles.

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.

Respiratory protection If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL, suitable respiratory protection must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134.

Thermal hazards None.

General hygiene considerations When using, do not eat, drink or smoke. Do not get this material on clothing. Wash hands after handling and before eating. Keep away from food and drink. Wash hands after handling. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Powder.

Color Not available.

Odor Not available.

Odor threshold Not applicable.

pH Not applicable.

Melting point/freezing point Not applicable.

Initial boiling point and boiling range Not applicable.

Flash point Not applicable.

Evaporation rate Not applicable.

Flammability (solid, gas) Non combustible.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not applicable.

Flammability limit - upper (%) Not applicable.

Vapor pressure Not applicable.

Vapor density	Not applicable.
Relative density	Not applicable.
Solubility(ies)	
Solubility (water)	Not applicable.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not applicable.
Viscosity	Not applicable.
Other information	
Density	Not applicable.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	High temperatures. Avoid dust formation. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None under normal temperatures and pressures.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Causes serious eye irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Under normal conditions of intended use, this material does not pose a risk to health.

Information on toxicological effects

Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Causes serious eye irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity	Due to lack of data the classification is not possible.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity	May damage fertility or the unborn child. Boric acid: High doses have demonstrated effects on fertility, testes, and developmental effects on the fetus in laboratory animals. Relevance of these findings to humans is uncertain.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Chronic effects	Prolonged skin contact may cause dermatitis.
Further information	As supplied, the product is expected to pose no immediate health or fire hazard.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	The product contains inorganic compounds which are not biodegradable.
Bioaccumulative potential	Not relevant for inorganic substances.
Mobility in soil	No data available.
Other adverse effects	The product is not volatile but may be spread by dust-raising handling.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Borax decahydrate (CAS 1303-96-4)

US. New Jersey Worker and Community Right-to-Know Act

Borax decahydrate (CAS 1303-96-4)
Boric acid (CAS 11113-50-1)

US. Pennsylvania Worker and Community Right-to-Know Law

Borax decahydrate (CAS 1303-96-4)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 17-May-2016

Revision date -

Version # 01

HMIS® ratings

Health: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings

References

HSDB® - Hazardous Substances Data Bank
ACGIH: American Conference of Governmental and Industrial Hygienists.
US. IARC Monographs on Occupational Exposures to Chemical Agents
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
IARC Monographs. Overall Evaluation of Carcinogenicity

Disclaimer

BD Diagnostics Preanalytical Systems cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.

SAFETY DATA SHEET

1. Identification

Product identifier **BD Vacutainer® Plasma Prep Tubes (PPT*TM*)**

Other means of identification

Product code 362788, 362791, 362794, 362795, 362799, 362800

Recommended use For blood collection and analysis.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name BD Diagnostics, PreAnalytical Systems

Address 1 Becton Drive
Franklin Lakes, NJ 07417-1885

Telephone 800-631-0174

Contact person Technical Services

Emergency telephone Chemtrec US 1-800-424-9300 EU 703-527-3887

E-mail pas_tech_services@bd.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement This material is not considered hazardous by the OSHA Hazard Communication Standard, OSHA 29 CFR 1910.1200.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Hydrophobic amorphous fumed silica	68611-44-9	1-5

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.
Components not listed are either non-hazardous or are below reportable limits.

4. First-aid measures

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Wash skin with soap and water. Get medical attention if irritation persists after washing.

Eye contact Flush eyes with water as a precaution. If irritation occurs, get medical assistance.

Ingestion Rinse mouth. Get medical attention if any discomfort occurs.

Most important symptoms/effects, acute and delayed	This product is not expected to produce adverse effects under normal conditions of use and appropriate personal hygiene.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases may be formed.
Special protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Material may burn when exposed to sufficient heat.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid contact with eyes and prolonged skin contact. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	Wipe up spilled material and place in a suitable container for disposal. Following product recovery, flush area with water. For waste disposal, see Section 13 of the SDS.
Environmental precautions	Environmental manager must be informed of all major spillages.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes and prolonged skin contact. Observe good laboratory hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in a cool, dry, well-ventilated place. Keep container closed. Store away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Hydrophobic amorphous fumed silica (CAS 68611-44-9)	TWA	6 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure limits noted for ingredient(s).
Appropriate engineering controls	General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection	Risk of contact: Wear approved safety goggles.
Skin protection	
Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier.
Skin protection	
Other	No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.
Respiratory protection	Under normal conditions, respirator is not normally required.
Thermal hazards	None.

General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	
Physical state	Gel..
Form	Tubes.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not applicable.
Flammability limit - upper (%)	Not applicable.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None expected under normal conditions of use.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Under normal conditions of intended use, this material does not pose a risk to health.
Eye contact	Under normal conditions of intended use, this material does not pose a risk to health.
Ingestion	Under normal conditions of intended use, this material does not pose a risk to health. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics This product is not expected to produce adverse effects under normal conditions of use and appropriate personal hygiene.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Components	Species	Test Results
Hydrophobic amorphous fumed silica (CAS 68611-44-9)		
Acute		
Inhalation		
LC50	Rat	0.45 mg/l, 4 hours

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Due to lack of data the classification is not possible.

Carcinogenicity

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrophobic amorphous fumed silica (CAS 68611-44-9) 3 Not classifiable as to carcinogenicity to humans.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Due to the physical form of the product it is not an aspiration hazard.

Chronic effects None known.

12. Ecological information

Ecotoxicity The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data available.

Bioaccumulative potential

Mobility in soil No data available.

Mobility in general No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Do not discharge into drains, water courses or onto the ground.

Hazardous waste code Not regulated.

Waste from residues / unused products Dispose of waste and residues in accordance with local authority requirements.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Hydrophobic amorphous fumed silica (CAS 68611-44-9)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Hydrophobic amorphous fumed silica (CAS 68611-44-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 18-March-2016

Revision date	-
Version #	01
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	
List of abbreviations	LC50: Lethal Concentration, 50%.
References	ACGIH: American Conference of Governmental and Industrial Hygienists. US. IARC Monographs on Occupational Exposures to Chemical Agents IARC Monographs. Overall Evaluation of Carcinogenicity National Toxicology Program (NTP) Report on Carcinogens ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
Disclaimer	To the best of our knowledge, the information contained herein is accurate. However, neither BD nor any of its subsidiaries assumes any liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Version: 1.0
Last revised date: 03/15/2017

Becton, Dickinson and Company
BD, Franklin Lakes, NJ
07417 USA
www.bd.com

SAFETY DATA SHEET

1. Identification

Product identifier

Product name: TUBE GLU PLH 13X75 2.0 PLBL GR **Product No.:** 367921

Synonyms, Trade Names: BD Vacutainer® Fluoride Blood Collection Tube for Glucose Determination

Other means of identification

Synonyms:	BD Vacutainer® Fluoride Blood Collection Tube for Glucose Determination
SDS number:	088100181047

Recommended use and restriction on use

Recommended use: Scientific and industrial laboratory use. For In Vitro Diagnostic Use.
Restrictions on use: For External Use Only

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name:	BD Diagnostics, Preanalytical Systems
Address:	1 Becton Drive 07417 Franklin Lakes, NJUSA
Telephone:	1 800 631 0174
Fax:	1 201 847 4866
Contact Person:	Technical Services
E-mail:	pas_tech_services@bd.com

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Health Hazards

Acute toxicity (Oral)	Category 3
Acute toxicity (Dermal)	Category 4
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2A

Unknown toxicity - Health

Acute toxicity, oral	0 %
Acute toxicity, dermal	0 %
Acute toxicity, inhalation, vapor	44.5 %
Acute toxicity, inhalation, dust or mist	44.5 %

Unknown toxicity - Environment

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07417 USA
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Acute hazards to the aquatic environment	44.5 %
Chronic hazards to the aquatic environment	44.5 %

Label Elements

Hazard Symbol:

Signal Word: Danger

Hazard Statement:
Toxic if swallowed.
Harmful in contact with skin.
Causes skin irritation.
Causes serious eye irritation.

Precautionary Statements

Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth. Call a POISON CENTER/doctor if you feel unwell. Specific treatment (see this label). Wash contaminated clothing before reuse.

Storage: Store locked up.

Disposal: Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

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Mixtures

Chemical Identity	Common name and synonyms	CAS number	Content in percent (%)*
Sodium fluoride (NaF)		7681-49-4	>=54 - <=56%
Ethanedioic acid, potassium salt (1:2)		583-52-8	>=44 - <=46%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

General information: No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, GET MEDICAL ATTENTION PROMPTLY!

Ingestion: Not likely, due to the form of the product. However: If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention immediately.

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin Contact: Due to the small packaging the risk of skin contact is minimal. However: Flush skin thoroughly with water. If skin irritation occurs: Get medical advice/attention. Call a POISON CENTER/doctor/.../if you feel unwell.

Eye contact: Due to the small packaging the risk of eye contact is minimal. However: In the event of contact with the eyes, rinse thoroughly with clean water. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Most important symptoms/effects, acute and delayed

Symptoms: May cause skin and eye irritation. May cause abdominal pain with vomiting, nausea, diarrhea, or dizziness.

Hazards: Low hazard for recommended handling by trained personnel.

Indication of immediate medical attention and special treatment needed

Treatment: Get medical advice/attention if you feel unwell.

5. Fire-fighting measures

General Fire Hazards: No unusual fire or explosion hazards noted.

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Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:	Water spray, fog, CO2, dry chemical, or alcohol resistant foam.
Unsuitable extinguishing media:	None known.
Specific hazards arising from the chemical:	None known.

Special protective equipment and precautions for firefighters

Special fire fighting procedures:	No unusual fire or explosion hazards noted.
Special protective equipment for fire-fighters:	No specific precautions due to the small quantities handled. Use fire-extinguishing media appropriate for surrounding materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:	Use personal protective equipment. Avoid contact with spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Methods and material for containment and cleaning up:	Sweep or scoop up and remove.
Environmental Precautions:	Avoid release to the environment.

7. Handling and storage

Precautions for safe handling:	Low hazard for recommended handling by trained personnel. Observe good laboratory hygiene practices.
Conditions for safe storage, including any incompatibilities:	Store in a cool, dry place out of direct sunlight. Store at specified temperature.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

Chemical Identity	type	Exposure Limit Values	Source
Sodium fluoride (NaF) - as F	TWA	2.5 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)

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	TWA	2.5 mg/m3	US. ACGIH Threshold Limit Values (12 2010)
	REL	2.5 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	PEL	2.5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Sodium fluoride (NaF) - Dust.	TWA	2.5 mg/m3	US. OSHA Table Z-2 (29 CFR 1910.1000) (02 2006)

Biological Limit Values

Chemical Identity	Exposure Limit Values	Source
Sodium fluoride (NaF) (Fluoride: Sampling time: Prior to shift.)	2 mg/l (Urine)	ACGIH BEI (03 2013)
Sodium fluoride (NaF) (Fluoride: Sampling time: End of shift.)	3 mg/l (Urine)	ACGIH BEI (03 2013)

Appropriate Engineering Controls Low hazard for recommended handling by trained personnel. Observe good industrial hygiene practices.

Individual protection measures, such as personal protective equipment

General information: No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals.

Eye/face protection: It is a good industrial hygiene practice to minimize eye contact.

Skin Protection

Hand Protection: Use suitable protective gloves if risk of skin contact.

Other: It is a good industrial hygiene practice to minimize skin contact. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory Protection: Not relevant, due to the form of the product. None should be needed.

Hygiene measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state: solid
Form: Powder
Color: White
Odor: Odorless
Odor threshold: No data available.
pH: No data available.
Melting point/freezing point: The physical-chemical properties of this material have not

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	been fully investigated.
Initial boiling point and boiling range:	The physical-chemical properties of this material have not been fully investigated.
Flash Point:	not applicable
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Upper/lower limit on flammability or explosive limits	
Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Explosive limit - upper (%):	No data available.
Explosive limit - lower (%):	No data available.
Vapor pressure:	The physical-chemical properties of this material have not been fully investigated.
Vapor density:	No data available.
Relative density:	The physical-chemical properties of this material have not been fully investigated.
Solubility(ies)	
Solubility in water:	The physical-chemical properties of this material have not been fully investigated.
Solubility (other):	not applicable
Partition coefficient (n-octanol/water):	The physical-chemical properties of this material have not been fully investigated.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	Not determined.

10. Stability and reactivity

Reactivity:	Stable under normal temperature conditions and recommended use.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	None under normal conditions.
Conditions to avoid:	None known. None under normal conditions.
Incompatible Materials:	No common materials and contaminants with which the material may reasonably come into contact.
Hazardous Decomposition Products:	Not likely, due to the form of the product.

11. Toxicological information

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General information: Under normal conditions of intended use, this material does not pose a risk to health.

Information on likely routes of exposure

Ingestion: Expected to be a low ingestion hazard.

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin Contact: Due to the small packaging the risk of skin contact is minimal.

Eye contact: Due to the small packaging the risk of eye contact is minimal.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion: No specific symptoms noted. However, ingestion may cause nausea, headache, dizziness and intoxication.

Inhalation: No specific symptoms noted.

Skin Contact: Causes skin irritation.

Eye contact: Causes serious eye irritation.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: ATEmix: 173.66 mg/kg

Dermal
Product: ATEmix: 1,466.18 mg/kg

Inhalation
Product: No data available.

Repeated dose toxicity
Product: No data available.

Skin Corrosion/Irritation
Product: No data available.

Serious Eye Damage/Eye Irritation
Product: No data available.

Specified substance(s):
Sodium fluoride (NaF) Possibly Irritating

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Respiratory or Skin Sensitization

Product: No data available.

Specified substance(s):

Sodium fluoride (NaF) Skin sensitization, in vivo (Guinea pig): Not a skin sensitizer.

Carcinogenicity

Product: No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product: No data available.

In vivo

Product: No data available.

Reproductive toxicity

Product: No data available.

Specific Target Organ Toxicity - Single Exposure

Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure

Product: No data available.

Aspiration Hazard

Product: No data available.

Other effects: No data available.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

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Fish
Product: No data available.

Specified substance(s):
Sodium fluoride (NaF) LC 50 (Fathead minnow (Pimephales promelas), 96 h): 124 - 194 mg/l Mortality

Aquatic Invertebrates
Product: No data available.

Specified substance(s):
Sodium fluoride (NaF) LC 50 (Water flea (Daphnia magna), 48 h): 335 mg/l Intoxication

Chronic hazards to the aquatic environment:

Fish
Product: No data available.

Aquatic Invertebrates
Product: No data available.

Toxicity to Aquatic Plants
Product: No data available.

Persistence and Degradability

Biodegradation
Product: No data available.

BOD/COD Ratio
Product: No data available.

Bioaccumulative potential
Bioconcentration Factor (BCF)
Product: No data available.

Partition Coefficient n-octanol / water (log Kow)
Product: Log Kow: The physical-chemical properties of this material have not been fully investigated.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

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Sodium fluoride (NaF)	No data available.
Ethanedioic acid, potassium salt (1:2)	No data available.

Other adverse effects: No data available.

13. Disposal considerations

Disposal instructions: Dispose of waste and residues in accordance with local authority requirements.

Contaminated Packaging: No data available.

14. Transport information

DOT

Special precautions for user: Not regulated.

IMDG

Special precautions for user: Not regulated.

IATA

Special precautions for user: Not regulated.

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

Chemical Identity	Reportable quantity
Sodium fluoride (NaF)	1000 lbs.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate (Acute) Health Hazards

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

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SARA 304 Emergency Release Notification

Chemical Identity	Reportable quantity
Sodium fluoride (NaF)	1000 lbs.

SARA 311/312 Hazardous Chemical

Chemical Identity	Threshold Planning Quantity
Sodium fluoride (NaF)	10000 lbs
Ethanedioic acid, potassium salt (1:2)	10000 lbs

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

Chemical Identity	Reportable quantity
Sodium fluoride (NaF)	Reportable quantity: 1000 lbs.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient regulated by CA Prop 65 present.

US. New Jersey Worker and Community Right-to-Know Act

Chemical Identity
Sodium fluoride (NaF)

US. Massachusetts RTK - Substance List

Chemical Identity
Sodium fluoride (NaF)

US. Pennsylvania RTK - Hazardous Substances

Chemical Identity
Sodium fluoride (NaF)

US. Rhode Island RTK

Chemical Identity
Sodium fluoride (NaF)

16.Other information, including date of preparation or last revision

Issue Date: 03/15/2017

Version #: 1.0

Version: 1.0
Last revised date: 03/15/2017

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Revision Information:

Further Information: No data available.

Disclaimer:

Disclaimer:
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SAFETY DATA SHEET

1. Identification

Product identifier **BD Vacutainer® SST Tubes**

Other means of identification

Product code 367782, 365967, 365968, 365978, 365979, 365906, 367966, 367968, 367974, 367976, 367977, 367979, 367981, 367983, 367985, 367986, 367987, 367988, 367989, 367991, 367997, 368013, 368015, 368016, 368159, 368825, 365979

Recommended use Blood collection (In-Vitro Diagnostic) device

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name BD Diagnostics, PreAnalytical Systems

Address 1 Becton Drive
Franklin Lakes, NJ 07417-1885

Telephone 800-631-0174

Contact person Technical Services

Emergency telephone Chemtrec US 1-800-424-9300 EU 703-527-3887

E-mail pas_tech_services@bd.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement This material is not considered hazardous by the OSHA Hazard Communication Standard, OSHA 29 CFR 1910.1200.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Hydrophobic amorphous fumed silica	68611-44-9	1-5
Quartz	14808-60-7	0.1-<1.0

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. Components not listed are either non-hazardous or are below reportable limits.

4. First-aid measures

Inhalation	Due to the small packaging the risk of inhalation is minimal. In case of risk of inhalation of vapor/aerosols: Move person to fresh air.
Skin contact	Wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyelids wide apart. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if any discomfort occurs.
Most important symptoms/effects, acute and delayed	May irritate eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases may be formed.
Special protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Material may burn when exposed to sufficient heat.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid inhalation of vapors. Avoid contact with eyes and prolonged skin contact. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	Wipe up spilled material and place in a suitable container for disposal. Following product recovery, flush area with water. For waste disposal, see Section 13 of the SDS.
Environmental precautions	Environmental manager must be informed of all major spillages.

7. Handling and storage

Precautions for safe handling	Avoid inhalation of vapors. Avoid contact with eyes and prolonged skin contact. Observe good laboratory hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in a cool, dry, well-ventilated place. Keep container closed. Store away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Quartz (CAS 14808-60-7)	TWA	0.3 mg/m3	Total dust.
		0.1 mg/m3	Respirable.
		2.4 mppcf	Respirable.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Quartz (CAS 14808-60-7)	TWA	0.025 mg/m3	Respirable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Hydrophobic amorphous fumed silica (CAS 68611-44-9)	TWA	6 mg/m3	
Quartz (CAS 14808-60-7)	TWA	0.05 mg/m3	Respirable dust.

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines No exposure limits noted for ingredient(s).

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Risk of contact: Wear approved safety goggles.

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.

Respiratory protection Under normal conditions, respirator is not normally required. If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

Thermal hazards None.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

Color Yellow.

Odor Odorless.

Odor threshold Not applicable.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not applicable.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not applicable.

Flammability limit - upper (%) Not applicable.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) No data available.

Auto-ignition temperature Not applicable.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None expected under normal conditions of use.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Due to the small packaging the risk of inhalation is minimal. However: Vapors may irritate throat and respiratory system and cause coughing.
Skin contact	May cause skin irritation.
Eye contact	May cause eye irritation.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	May irritate eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Components	Species	Test Results
Hydrophobic amorphous fumed silica (CAS 68611-44-9)		
Acute		
Inhalation		
LC50	Rat	0.45 mg/l, 4 hours

Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity	Inhalation of quartz dust may cause cancer, however due to the physical form of the product, inhalation of dust is not likely.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrophobic amorphous fumed silica (CAS 68611-44-9)	3 Not classifiable as to carcinogenicity to humans.
Quartz (CAS 14808-60-7)	1 Carcinogenic to humans.

NTP Report on Carcinogens

Quartz (CAS 14808-60-7)	Known To Be Human Carcinogen.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity	Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Due to lack of data the classification is not possible.
Chronic effects	None known.

12. Ecological information

Ecotoxicity The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data available.

Bioaccumulative potential

Mobility in soil No data available.

Mobility in general No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Do not discharge into drains, water courses or onto the ground.

Hazardous waste code Not regulated.

Waste from residues / unused products Dispose of waste and residues in accordance with local authority requirements.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Toluene (CAS 108-88-3) LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Toluene (CAS 108-88-3)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number

Toluene (CAS 108-88-3) 6594

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Toluene (CAS 108-88-3) 35 %WV

DEA Exempt Chemical Mixtures Code Number

Toluene (CAS 108-88-3) 594

US state regulations WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Hydrophobic amorphous fumed silica (CAS 68611-44-9)
Quartz (CAS 14808-60-7)
Toluene (CAS 108-88-3)

US. New Jersey Worker and Community Right-to-Know Act

Quartz (CAS 14808-60-7)
Toluene (CAS 108-88-3)

US. Pennsylvania Worker and Community Right-to-Know Law

Hydrophobic amorphous fumed silica (CAS 68611-44-9)
Quartz (CAS 14808-60-7)
Toluene (CAS 108-88-3)

US. Rhode Island RTK

Toluene (CAS 108-88-3)

US. California Proposition 65

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Quartz (CAS 14808-60-7)
Toluene (CAS 108-88-3)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-October-2015

Revision date 09-March-2016

Version # 02

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 1
Flammability: 1
Physical hazard: 0

NFPA ratings

List of abbreviations LC50: Lethal Concentration, 50%.

References ACGIH: American Conference of Governmental and Industrial Hygienists.
US. IARC Monographs on Occupational Exposures to Chemical Agents
IARC Monographs. Overall Evaluation of Carcinogenicity
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices

Disclaimer	To the best of our knowledge, the information contained herein is accurate. However, neither BD nor any of its subsidiaries assumes any liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
This SDS contains revisions in the following section(s):	1, 16.

BECKMAN COULTER
BICARBONATE

SAFETY DATA SHEET

Document ID: OSR6190-75 Version 06
Revision Date (year/month/day) 2019/08/07
Last Revision Date (year/month/day) 2016/10/21

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name BICARBONATE

Part Number OSR6190, OSR6290

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow tint; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA
NIOSH	None established
Japan	None established
Sweden (AFS 2015:7 and amendments)	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Yellow tint	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	8.75	**Partition n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

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Section 11 Toxicological Information (Continued)

Acute Toxicity	Not	based on available data.
Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	Not	based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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BECKMAN COULTER
BICARBONATE

SAFETY DATA SHEET

Document ID: OSR6190-75 Version 06
Revision Date (year/month/day) 2019/08/07
Last Revision Date (year/month/day) 2016/10/21

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 8, 11, 15, 16.

Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2019/08/07

Last Revision Date (year/month/day) 2016/10/21

Document ID: OSR6190-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

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BICARBONATE

SAFETY DATA SHEET

Document ID: OSR6190-75 Version 06
Revision Date (year/month/day) 2019/08/07
Last Revision Date (year/month/day) 2016/10/21

Section 16 Other Information (Continued)

vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER
Bicarbonate Calibrator (L1 and L2)

SAFETY DATA SHEET

Document ID: ODC0019-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Bicarbonate Calibrator (L1 and L2)

Part Number ODC0019

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

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BECKMAN COULTER
Bicarbonate Calibrator (L1 and L2)

SAFETY DATA SHEET

Document ID: ODC0019-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Carbonate CAS # 497-19-8 EINECS # 207-838-8 Index # 011-005-00-2	1 - 5	Eye Irrit. 2, H319	Eye Irrit. 2, H319	3, 8
Sodium Ortho-Phenylphenate CAS # 132-27-4 EINECS # 205-055-6 Index # 604-021-00-1	0.1 - 0.5	Acute Tox. Oral 4, H302 Aquatic Acute 1, H400 Eye Dam. 1, H318 STOT SE 3, H335 Skin Irrit. 2, H315	Acute Tox. Oral 4, H302 Aquatic Acute 1, H400 Eye Dam. 1, H318 STOT SE 3, H335 Skin Irrit. 2, H315	4, 8

3 - Health hazard
4 - Environmental hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 15 to 25°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Sodium Ortho-Phenylphenate CAS # 132-27-4	2 mg/m3 Peak; 2 mg/m3 TWA MAK
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established
Sweden (AFS 2015:7 and amendments)	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	10.8	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Ortho-Phenylphenate CAS # 132-27-4	Oral LD50 Rat 1000 mg/kg
Sodium Carbonate CAS # 497-19-8	Oral LD50 Rat 4090 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	This product contains Sodium Ortho-Phenylphenate listed as IARC group 2B (possibly carcinogenic to humans).
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Carbonate
CAS # 497-19-8: 96 h LC50 Lepomis macrochirus: 300 mg/L [static]; 96 h LC50 Pimephales promelas: 310 - 1220 mg/L [static]

Microtox No information available.

Water Flea

Sodium Carbonate
CAS # 497-19-8: 48 h EC50 Daphnia magna: 265 mg/L

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 132-27-4 Sodium Ortho-Phenylphenate 0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 132-27-4 Sodium Ortho-Phenylphenate

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 132-27-4 Sodium Ortho-Phenylphenate

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 132-27-4 Sodium Ortho-Phenylphenate

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated Section 4, 6, 8, 11 - 16.
Updated Section 10.

Document version and issue/revision date

Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20
Document ID: ODC0019-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.

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Section 16 Other Information (Continued)

H335 - May cause respiratory irritation.

H400 - Very toxic to aquatic life.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LD50 - Lethal Dose, 50%

LC50 - Lethal Concentration, 50%

EC50 - Effective Concentration, 50%

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Kit SDS Cover Sheet

Document ID: OSR6134-75: Version 11
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2018/03/16

Product Information

Product Name	Urea Nitrogen OSR6134, OSR6234, OSR6634 Urea Nitrogen (BUN) STAT OSR6141, OSR6641
Part Number	OSR6134, OSR6141, OSR6234, OSR6634, OSR6641

Components

Description	Urea Nitrogen R1 OSR6134, OSR6234, OSR6634 Urea Nitrogen (BUN) STAT R1 OSR6141, OSR6641 Urea Nitrogen R2 OSR6134, OSR6234, OSR6634 Urea Nitrogen (BUN) STAT R2 OSR6141, OSR6641

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6134-75 Version 11
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2018/03/16

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urea Nitrogen R1 OSR6134, OSR6234, OSR6634

Urea Nitrogen (BUN) STAT R1 OSR6141, OSR6641

Part Number Component of P/N OSR6134, OSR6141, OSR6234, OSR6634, OSR6641

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Skin Corr. 1B, H314 Skin Sens. 1, H317	15, 8

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Urea Nitrogen OSR6134, OSR6234, OSR6634
Urea Nitrogen (BUN) STAT OSR6141, OSR6641
Urea Nitrogen R1 OSR6134, OSR6234, OSR6634

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Last Revision Date (year/month/day) 2018/03/16

Section 3 Composition and Information on Ingredients (Continued)

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan	None established
Sweden (AFS 2015:7 and amendments)	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.00 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	10.2 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity — No further relevant information available.

10.2 Chemical Stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid — Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure — Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity — Not based on available data.

Skin Corrosion/Irritation — Not based on available data.

Serious eye damage/eye irritation — Not based on available data.

Respiratory/skin sensitization — This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity — No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity — Not based on available data.

Reproductive Toxicity — Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 3, 8, 11, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2018/03/16
Document ID: OSR6134-75
Version: 11

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

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Section 16 Other Information (Continued)

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urea Nitrogen R2 OSR6134, OSR6234, OSR6634
Urea Nitrogen (BUN) STAT R2 OSR6141, OSR6641

Part Number Component of P/N OSR6134, OSR6141, OSR6234, OSR6634, OSR6641

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com
Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887
Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.
Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Sodium Pyrophosphate, Decahydrate

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Tris(hydroxymethyl)– aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	2 - 5	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Sodium Pyrophosphate, Decahydrate CAS # 13472-36-1 EINECS # 231-767-1 Index # Not available	1 - 2	Eye Irrit. 2A, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2A, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

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Section 8 Exposure Controls and Personal Protection (Continued)

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of	uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.8 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	Metals and metallic compounds
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

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Section 11 Toxicological Information (Continued)

Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the label elements in Sec. 2.2.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated hazardous ingredients in Section 3.
Updated Section 8, 11, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12

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Section 16 Other Information (Continued)

Last Revision Date (year/month/day) 2018/03/16
Document ID: OSR6134-75
Version: 11

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Eye Irrit. 2A - Eye Irritation Category 2A
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

Urea Nitrogen OSR6134, OSR6234, OSR6634
Urea Nitrogen (BUN) STAT OSR6141, OSR6641
Urea Nitrogen R2 OSR6134, OSR6234, OSR6634

SAFETY DATA SHEET

Document ID: OSR6134-75 Version 11
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2018/03/16

Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6159-75: Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Product Information

Product Name	C3
Part Number	OSR6159

Components

Description	C3 R1 C3 R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

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SAFETY DATA SHEET

Document ID: OSR6159-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name C3 R1

Part Number Component of P/N OSR6159

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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C3
C3 R1

SAFETY DATA SHEET

Document ID: OSR6159-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 2 Hazards (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Tris(hydroxymethyl)– aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

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BECKMAN COULTER
C3
C3 R1

SAFETY DATA SHEET
Document ID: OSR6159-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan	None established
Sweden (AFS 2015:7 and amendments)	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	7.2	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	250°C (482°F)	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	Metals and metallic compounds
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

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Section 11 Toxicological Information (Continued)

Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated the label elements in Sec. 2.2. Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Updated hazardous ingredients in Section 3.	

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Section 16 Other Information (Continued)

Updated Section 4 - 8, 10, 11, 13 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12
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Document ID: OSR6159-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name C3 R2

Part Number Component of P/N OSR6159

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light orange; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Light orange	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the label elements in Sec. 2.2.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated hazardous ingredients in Section 3.
Updated Section 4, 6 - 8, 10, 11, 13 - 16.

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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6160-75: Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Product Information

Product Name	C4
Part Number	OSR6160

Components

Description	C4 R1 C4 R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name C4 R1

Part Number Component of P/N OSR6160

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Mild

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Tris(hydroxymethyl)– aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

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Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan	None established
Sweden (AFS 2015:7 and amendments)	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild	**Organic**	Not determined
pH	7.2	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	250°C (482°F)	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	Metals and metallic compounds
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

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Section 11 Toxicological Information (Continued)

Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated the label elements in Sec. 2.2. Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Updated hazardous ingredients in Section 3.	

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Section 16 Other Information (Continued)

Updated section 4, 8, 11, 14, 15, 16.

Document version and issue/revision date

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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name C4 R2

Part Number Component of P/N OSR6160

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light orange; Clear; Liquid; Mild

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements — **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03 @20°C
Color	Light orange	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the label elements in Sec. 2.2.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated hazardous ingredients in Section 3.
Updated section 4, 8, 11, 14, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20
Document ID: OSR6160-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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BECKMAN COULTER
C4
C4 R2

SAFETY DATA SHEET

Document ID: OSR6160-75 Version 04
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER
Calcium Arsenazo

SAFETY DATA SHEET

Document ID: OSR61117 Version 10
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Calcium Arsenazo

Part Number OSR60117, OSR61117, OSR66117

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.
Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Lismeehan O'Callaghan's Mills Co. Clare Ireland Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com
Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887
Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.
Pink; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Skin Irritation Category 2
Toxic to Reproductive Category 1
Eye Irritation Category 2

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 2
Toxic to Reproductive Category 1
Eye Irritation Category 2

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BECKMAN COULTER
Calcium Arsenazo

SAFETY DATA SHEET

Document ID: OSR61117 Version 10
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

2-Chloroacetamide

Imidazole

Pictogram

Signal Word

DANGER

Hazard Statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H360 May damage fertility or the unborn child.

EUH208 May produce an allergic reaction.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Imidazole CAS # 288-32-4 EINECS # 206-019-2 Index # Not available	1 - 2	Acute Tox. Oral 4, H302 Repr. 1B, H360 Skin Corr. 1C, H314	Acute Tox. Oral 4, H302 Repr. 1B, H360 Skin Corr. 1C, H314	
2,7-(bis(2-arsonophenylazo))-1, 8-dihydroxynaphthalene- 3,6-disulphonic acid CAS # 1668-00-4 EINECS # 216-788-6 Index # 033-002-00-5	0.1 - 0.2	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	3, 4, 8
Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # 618-344-0 Index # Not available	0.1 - 1	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	8, SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
2-Chloroacetamide CAS # 79-07-2 EINECS # 201-174-2 Index # 616-036-00-0	< 0.1	Acute Tox. Oral 3, H301 Repr. 2, H361 Skin Sens. 1, H317	Acute Tox. Oral 3, H301 Aquatic Acute 3, H402 Repr. 2, H361 Skin Sens. 1, H317	15, 8

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
3 - Health hazard
4 - Environmental hazard
8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. If pain or irritation occurs, obtain medical advice/attention.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Calcium Arsenazo

Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

May damage fertility or the unborn child.

May cause skin and eyes irritation.

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

2,7-(bis(2-arsonophenylazo))-1, 8-dihydroxynaphthalene-3,6-disulphonic acid CAS # 1668-00-4	0.5 mg/m3 TWA (As Arsenic, organic compounds [RR-00035-1]) (as As)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

2-Chloroacetamide CAS # 79-07-2	skin notation
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

2,7-(bis(2-arsonophenylazo))-1, 8-dihydroxynaphthalene-3,6-disulphonic acid CAS # 1668-00-4	0.01 mg/m3 TWA (except Arsine) (as As); 0.03 mg/m3 STEL (calculated) (as As)
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.004 @20°C
Color	Pink	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	6.9	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid

Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Imidazole CAS # 288-32-4	Oral LD50 Rat 220 mg/kg
2-Chloroacetamide CAS # 79-07-2	Oral LD50 Rat 138 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation May cause skin irritation.

Serious eye damage/eye irritation May cause eye irritation.

Respiratory/skin sensitization This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity May damage fertility or the unborn child.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide
CAS # 26628-22-8
96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

Microtox No information available.

Water Flea

Imidazole
CAS # 288-32-4
48 h EC50 Daphnia magna: 341.5 mg/L

Fresh Water Algae

Imidazole
CAS # 288-32-4
72 h EC50 Desmodesmus subspicatus: 130 mg/L; 96 h EC50 Desmodesmus subspicatus: 82 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration
CAS # 1668-00-4	2,7-(bis(2-arsonophenylazo))-1, 8-dihydroxynaphthalene-3,6-disulphonic acid	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

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Calcium Arsenazo

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Document ID: OSR61117 Version 10
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 15 Regulatory Information (Continued)

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 1668-00-4	2,7-(bis(2-arsonophenylazo))-1, 8-dihydroxynaphthalene- 3,6-disulphonic acid

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide
CAS # 1668-00-4	2,7-(bis(2-arsonophenylazo))-1, 8-dihydroxynaphthalene- 3,6-disulphonic acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1 Updated E-mail address in Sec. 1.3. Updated Section 1. Updated Section 8, 11, 15, 16. Updated Section 12.	

Document version and issue/revision date

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Section 16 Other Information (Continued)

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08
Document ID: OSR61117
Version: 10

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Aquatic Acute 3 - Aquatic Hazard Acute, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1 - Skin Sensitization Category 1
Repr. 1B - Toxic to Reproductive Category 1B
Repr. 2 - Toxic to Reproductive Category 2
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H360 - May damage fertility or the unborn child.
H361 - Suspected of damaging fertility or the unborn child.
H400 - Very toxic to aquatic life.
H402 - Harmful to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values

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Calcium Arsenazo

SAFETY DATA SHEET

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Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 16 Other Information (Continued)

NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Doc. ID: 33200-75: Rev. AF
Revised (year/month/day) 2015/03/31

Product Information

Product Name	CEA
Part Number	33200
Series Name	ACCESS®

Components

Description

PMP (Compartment R1a)
Diluent (Compartment R1b)
Conjugate (Compartment R1c)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 33200-75 Rev. AF
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PMP (Compartment R1a)

Part Number Component of P/N 33200

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH — None established

Japan — None established

8.2 Exposure controls

Engineering Controls — No special engineering controls are required. Use with good general ventilation.

Eye Protection — Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection — Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection — Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	Not determined
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.4	**Partition coefficient: n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes skin irritation.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	Causes eye irritation
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B

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Section 16 Other Information (Continued)

	Skin Sens. 1 - Skin Sensitization Category 1 H300 - Fatal if swallowed. H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: 33200-75 Rev. AF
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Diluent (Compartment R1b)

Part Number Component of P/N 33200

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Eye Damage Category 1
Skin Sensitization Category 1
Aquatic Hazard Long term, Category 3

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43; R52/53

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Eye Damage Category 1
Aquatic Hazard Long term, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Polyoxyethylated Octyl Phenol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

DANGER

Hazard Statements

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard Classification of Pure Ingredients

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Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # Not available Index # Not available	1 - 5	Xn;R22-41 N;R51/53	Acute Tox. Oral 4 Aquatic Longterm 2 Eye Dam. 1 H302; H318; H411	Acute Tox. Oral 4 Aquatic Longterm 2 Eye Dam. 1 H302; H318; H411	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	Not determined
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation Causes skin irritation.

Serious eye damage/eye irritation Causes eye irritation

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

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Section 12 Ecological Information (Continued)

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

Pennsylvania RTK
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S37 Wear suitable gloves.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List
Citric Acid
Polyoxyethylated Octyl Phenol
Sodium Azide

Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Xn - Harmful
R22 Harmful if swallowed.
R41 Risk of serious damage to eyes.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

*ProClin is a trademark of the Rohm and Haas Company.

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33200-75 Rev. AF
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Conjugate (Compartment R1c)

Part Number Component of P/N 33200

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	Not determined
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.

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Section 11 Toxicological Information (Continued)

Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Citric Acid
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

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Section 16 Other Information (Continued)

	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 Skin Corr. 1B - Skin Corrosion Category 1B Skin Sens. 1 - Skin Sensitization Category 1 H300 - Fatal if swallowed. H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

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CETYLITE® SAFETY DATA SHEET

Cetylcide II

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

1.1 Trade Name (as labeled): **Cetylcide II**
Synonyms: N/A
CAS No: Mixture
1.2 Product Use: Hospital disinfectant
1.3 Company Name: **Cetylite**
Company Address: 9051 River Road
Company Address Cont: Pennsauken, NJ 08110
Business Phone: (800) 257-7740 or (856) 665-6111
Website: www.cetylite.com
1.4 Emergency Telephone Number: (800) 257-7740
Date of Current Revision: November 3, 2016
Date of Last Revision: August 27, 2013

SECTION 2 - HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product is a light yellow colored liquid with a slight pungent odor. Corrosive: May cause irreversible eye damage. Causes severe skin burns. Harmful if swallowed.
This product is a non-flammable liquid.
The Environmental effects of this product have not been investigated. Release of this product is anticipated to have adverse effects in the aquatic environment.

US DOT Symbols: None

EU and GHS Symbols:

Signal Word: Danger!

2.1 CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 or the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:
Index Number:
EC# 231-791-2 this substance is not classified in the Annex VI of Directive 67/548/EEC
EC# 269-919-4 this substance is not classified in the Annex VI of Directive 67/548/EEC
EC# 287-090-7 this substance is not classified in the Annex VI of Directive 67/548/EEC
EC# 207-838-8 Annex VI Index# 011-005-00-2
EC# 500-315-8 this substance is not classified in the Annex VI of Directive 67/548/EEC
EC# 200-573-9 Annex VI Index# 607-428-00-2
Substances not listed either individually or in group entries must be self classified.

Components Contributing to Classification: Alkyl dimethyl benzyl ammonium chloride, Alkyl dimethyl ethyl ammonium chloride, Sodium Carbonate Monohydrate, Nonylphenol polyethylene glycol ether, Tetrasodium Ethylenediamine Tetraacetate

2.2 Label Elements:

GHS Hazard Classifications:
Acute Toxicity Category 4 (Oral)
Skin Corrosion Category 1B
Eye Damage Category 1
Acute Aquatic Toxicity Category 2

Hazard Statements:
H302: Harmful if swallowed
H314: Causes severe skin burns and eye damage
H318: Causes serious eye damage
H401: Toxic to aquatic life

Prevention Statements:
P260: Do not breathe dusts or mists.
P264: Wash hands thoroughly after handling
P270: Do not eat, drink or smoke when using this product.
P280: Wear protective gloves/protective clothing/eye protection/face protection
P273 Avoid release to the environment

Response Statements:

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P330: Rinse mouth.
P363: Wash contaminated clothing before reuse.
P310 Immediately call a POISON CENTER/doctor if you feel unwell.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Storage Statements:

P405: Store locked up.

Disposal Statements:

P501 Dispose of contents/container in accordance with local/regional/ national/international regulations.

2.3 Other Hazards:

None Applicable

SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS No.	EINECS No.	Hazard Classification
Water	80 - 90%	7732-18-5	231-791-2	Not Classified
Alkyl dimethyl benzyl ammonium chloride	1 - 5%	68391-01-5	269-919-4	ACUTE TOX CAT 4 (ORAL), SKIN IRRITANT CAT 2, AQUATIC ACUTE CAT 1
Alkyl dimethyl ethyl ammonium chloride	1 - 5%	85409-23-0	287-090-7	ACUTE TOX CAT 4 (ORAL), SKIN CORROSIVE CAT 1, AQUATIC ACUTE CAT 1
Sodium Carbonate Monohydrate	1 - 5%	497-19-8	207-838-8	EYE IRRITANT CAT 2
Nonylphenol polyethylene glycol ether	1 - 5%	127087-87-0	500-315-8	SKIN IRRITANT CAT 2, EYE DAM 1, AQUATIC CHRONIC 3
Tetrasodium Ethylenediamine tetraacetate	1 - 5%	64-02-8	200-573-9	ACUTE TOX CAT 4 (ORAL) EYE DAM 1
Balance of other ingredients are non-hazardous or less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

Note: All WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR, EU Directives and the Japanese Industrial Standard JIS Z 7250:2000

SECTION 4 - FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye Contact:

If product enters the eyes, flush with plenty of water or eye wash solution for several minutes. Remove contacts if present and easy to do. Seek medical attention if irritation persists.

Skin Contact:

Wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

Inhalation:

If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

Ingestion:

If product is swallowed, call physician or poison center immediately. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

Medical Conditions Generally Aggravated by Exposure:

Pre-existing skin or eye problems may be aggravated by prolonged contact.

4.2 Symptoms and Effects Both Acute and Delayed:

Exposure to skin or eyes may cause damage.

4.3 Recommendations to Physicians:

Treat symptoms and eliminate overexposure.

SECTION 5 - FIRE FIGHTING MEASURES

5.1 Fire Extinguishing Materials:

Use the following fire extinguishing materials:

Water Spray: Yes **Carbon Dioxide:** Yes
Foam: Yes **Dry Chemical:** Yes
Halon: Yes **Other:** Any "C" Class

5.2 Unusual Fire and Explosion Hazards:

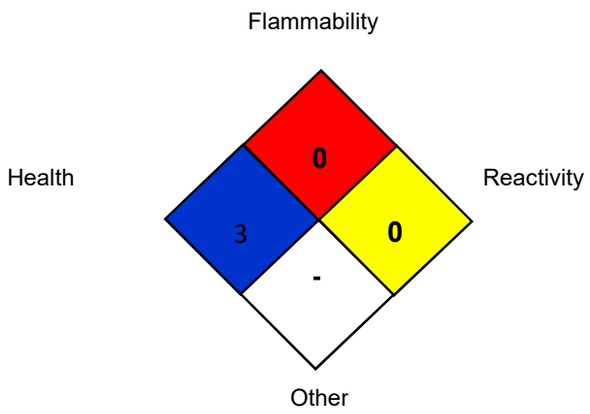
Flammable concentrations of vapor can accumulate above flash point listed above. Under fire conditions some components may decompose. The smoke may contain unidentified toxic and/or irritating compounds. The material will not burn until the water has evaporated.

Explosive Sensitivity to Mechanical Impact: No
Explosive Sensitivity to Static Discharge: No

5.3 Special Fire-Fighting Procedures:

- Incipient fire responders should wear eye protection.
- Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment.
- Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray.
- If possible, prevent run-off water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD (BLUE)	**3**
FLAMMABILITY HAZARD (RED)	**0**
PHYSICAL HAZARD (YELLOW)	**0**

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimum 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic Hazard

SECTION 6 - ACCIDENTAL RELEASE MEASURES (STEPS FOR SPILLS)

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Use cautious judgment when cleaning up spill. Wear suitable protective clothing, gloves, and eye/face protection.

6.2 Environmental Precautions:

Construct a dike to prevent spreading. Keep out of sewers, storm drains, surface waters, and soils.

6.3 Spill and Leak Response:

Small Spills:

- Collect material via broom or mop. Place in tightly sealed container for proper disposal. Approach spill areas with caution.

Large Spills:

- If liquid was introduced, create a dike or trench to contain material. Soak up with absorbent material such as clay, sand or other suitable non-reactive material.
- Place in leak-proof containers. Seal tightly for proper disposal.

- Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations and those of Canada and its Provinces, those of Australia, Japan and EU Member States (see Section 13, Disposal Considerations).

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

To prevent eye contact under the foreseeable conditions of use, wear appropriate safety eyewear. When handling, do not eat, drink, or smoke. Wash thoroughly after handling. Do not handle or store near heat, sparks, or flame.

7.2 Storage and Handling Practices:

Keep away from incompatible materials. Keep container closed when not in use and store in well ventilated area.

7.3 Specific Uses:

Hospital disinfectant.

SECTION 8 - EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Exposure Parameters:

Ingredients	CAS No.	OSHA PEL	NIOSH PEL
Water	7732-18-5	Not Listed	Not Listed
Alkyl dimethyl benzyl ammonium chloride	68391-01-5	Not Listed	Not Listed
Alkyl dimethyl ethyl ammonium chloride	85409-23-0	Not Listed	Not Listed
Sodium Carbonate Monohydrate	497-19-8	Not Listed	Not Listed
Nonylphenol polyethylene glycol ether	127087-87-0	Not Listed	Not Listed
Tetrasodium Ethylenediamine tetraacetate	64-02-8	Not Listed	Not Listed

8.2 Exposure Controls:

Ventilation and Engineering Controls: Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132), or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

Respiratory Protection: Maintain airborne contaminant concentrations below guidelines listed above, if applicable. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

Eye Protection: Safety glasses or goggles are recommended. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

Hand Protection: Chemical resistant gloves are recommended to prevent skin contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

Body Protection: Use body protect appropriate to task being performed. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance (Physical State and Color): This product is a light yellow colored liquid with a slight pungent odor.
Odor: Slight pungent odor
Odor Threshold: No data available
pH: 11.7
Melting/Freezing Point: No data available

Boiling Point: 212°F
Flash Point: No data available
Evaporation Rate: No data available
Flammability (Solid; Gas): No data available
Upper/Lower Flammability or Explosion Limits: No data available
Vapor Pressure (mm Hg @ 20°C (68° F): No data available
Vapor Density: No data available
Relative Density: Not Available
Specific Gravity: 1.03 @20°C
Solubility in Water: No data available
Weight per Gallon: No data available
Partition Coefficient (n-octanol/water): No data available
Auto-Ignition Temperature: No data available
Decomposition Temperature: No data available
Viscosity: <5%

9.2 Other Information: No data available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity: This product is not reactive.

10.2 Stability: Stable under conditions of normal storage and use.

10.3 Possibility of Hazardous Reactions: Not identified.

10.4 Conditions to Avoid: Contact with incompatible materials.

10.5 Incompatible Substances: Acids; strong oxidizing agents.

10.6 Hazardous Decomposition Products: When heated to decomposition this product may contain Nitrogen oxides; carbon monoxide; carbon dioxide; ammonia; hydrogen chloride.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Toxicity Data:

Tetrasodium Ethylenediamine tetraacetate	64-02-8	LD50 Dermal – Rabbit	>5,000 mg/kg

Acute toxicity	Acute Toxicity Category 4 (Oral)
Skin corrosion / irritation	Skin Corrosion Category 1B
Serious eye damage / irritation	Eye Damage Category 1
Respiratory or skin sensitization	Based on available data, the classification criteria are not met
Germ cell mutagenicity	Based on available data, the classification criteria are not met
Carcinogenicity	Based on available data, the classification criteria are not met
Reproductive toxicity	Based on available data, the classification criteria are not met
STOT-single exposure	Based on available data, the classification criteria are not met
STOT-repeated exposure	Based on available data, the classification criteria are not met
Aspiration hazard	Based on available data, the classification criteria are not met

Routes of Exposure:

Symptoms of Overexposure by Route of Exposure:

The most significant routes of overexposure for this product are by contact with skin or eyes, ingestion or inhalation. The symptoms of overexposure are described in the following paragraphs.

Acute:

Inhalation: Inhalation of vapors may cause irritation of the upper respiratory system.

Skin Contact: Brief contact with skin may cause skin irritation with local redness. Prolonged contact may cause severe skin burns.

Eye Contact: Vapours and direct contact to the eyes may be damaging.

Ingestion: Swallowing may result in irritation or burns of the mouth, throat and gastrointestinal system..

Chronic: None known

Target Organs:

Acute: Skin, Eyes, Respiratory System

Chronic: None known

Suspected Cancer Agent:	One of the ingredients are found on the following lists: FEDERAL OSHA Z LIST, NTP, CAL/OSHA, IARC and therefore is considered to be, or suspected to be a cancer-causing agent by these agencies. Contains trace amount of trisodium nitrilo triacetic acid which is listed as a potential carcinogen under OSHA Std. 20 CFR 1920.1200. Also listed by; NTP, IARC.
Irritancy:	Contact with this product can be irritating to exposed skin and eyes.
Sensitization to the Product:	This product is not expected to cause skin and respiratory sensitization.
Germ Cell Mutagenicity:	This product does not contain ingredients that are suspected to be a germ cell mutagenic.
Reproductive Toxicity:	This product is not expected to be a human reproductive toxicant.

SECTION 12 - ECOLOGICAL INFORMATION

12.1 Toxicity:	No specific data available on this product.
12.2 Persistence and Degradability:	No specific data available on this product.
12.3 Bioaccumulative Potential:	No specific data available on this product.
12.4 Mobility in Soil:	No specific data available on this product.
12.5 Results of PBT and vPvB Assessment:	No specific data available on this product.
12.6 Other Adverse Effects:	No data available.
12.7 Water Endangerment Class:	At present, there are no ecotoxicological assessments for this product.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:	Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Australia, EU Member States and Japan.
13.2 EU Waste Code:	Not determined

SECTION 14 - TRANSPORTATION INFORMATION

14.1 U.S. Department of Transportation (DOT) Shipping Regulations:

This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

UN Identification Number:	None
Proper Shipping Name:	None
Hazard Class Number and Description:	None
Packing Group:	None
DOT Label(s) Required:	None
North American Emergency Response Guidebook Number:	None

14.2 Environmental Hazards:

Marine Pollutant:	One of the ingredients are classified by the DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B)

14.3 Special Precaution for User:	None
14.4 International Air Transport Association Shipping Information (IATA):	This product is not considered as dangerous goods.
14.5 International Maritime Organization Shipping Information (IMO):	This product is not considered as dangerous goods.

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations Specific for the Substance or Mixture:

United States Regulations:

U.S. SARA Reporting Requirements:

The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act. None known

U.S. SARA 311/312:

Acute Health: Yes; Chronic Health: No; Fire: No; Reactivity; No

U.S. SARA 313: None known

U.S. CERCLA Reportable Quantity:

None known

U.S. TSCA Inventory Status:
The components of this product are listed on the TSCA Inventory or are exempted from listing.
Other U.S. Federal Regulations:
None known
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does not contain ingredients on the Proposition 65 Lists.

15.2 Canadian Regulations:

Canadian DSL/NDSL Inventory Status:
Components are DSL Listed, NDSL Listed and/or are exempt from listing
Other Canadian Regulations:
Not applicable
Canadian Environmental Protection Act (CEPA) Priorities Substances Lists:
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
Canadian WHMIS Classification and Symbols:
Classified per WHMIS 2015 Controlled Product Regulations.

15.3 European Economic Community Information:

This product meets the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives. See Section 2 for Details.
Chemical Safety Assessment:
No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

15.4 Australian Information for Product:

Components of this product are listed on the International Chemical Inventory list.

15.5 Japanese Information for Product:

Japanese Minister of International Trade and Industry (MITI) Status: The components of this product are not listed as Class I specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

15.6 International Chemical Inventories:

Listing of the components on individual country Chemical Inventories is as follows:
Australian Inventory of Chemical Substances (AICS): Listed
Korean Existing Chemicals List (ECL): Listed
Japanese Existing National Inventory of Chemical Substances (ENCS): Listed
Philippines Inventory if Chemicals and Chemical Substances (PICCS): Listed
U.S. TSCA: Listed

SECTION 16 - ADDITIONAL INFORMATION

Prepared By: Chris Eigbrett (MSDS to GHS Compliance)
Date of Printing: November 3, 2016

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. This safety sheet cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers. Cetylite assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Cetylite assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Compliance with all applicable federal, state, and local laws and local regulations remains the responsibility of the user.

Revision History:

March 8 2012 - Document creation.

November 3 2016 - Updated template with *corrected GHS elements and added data elements for EU compliance.*

END OF SDS SHEET

BECKMAN COULTER
Cholesterol

SAFETY DATA SHEET

Doc. ID: OSR6116-75 Rev. 07
Revised (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Cholesterol

Part Number OSR6116, OSR6216, OSR6616

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Pink; Clear; Liquid; Phenol odor

according to EC 1272/2008 (CLP/GHS)

Eye Irritation Category 2

according to EC Directives 1999/45/EC and 67/548/EEC

Not as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

Eye Irritation Category 2

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BECKMAN COULTER
Cholesterol

SAFETY DATA SHEET

Doc. ID: OSR6116-75 Rev. 07
Revised (year/month/day) 2017/05/08

Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated lauryl alcohol

Peroxidase

Phenol

Genapol X080

Pictogram

Signal Word

WARNING

Hazard Statements

H319 Causes serious eye irritation.

H316 Causes mild skin irritation.

EUH208 May produce an allergic reaction.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P337+P313 If eye irritation persists: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Product label will display most precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Genapol X080 CAS # 78330-21-9 EINECS # Not available Index # Not available	1.5 - 2.5	Xn;R22	Acute Tox. Oral 4 Aquatic Longterm 3 Eye Dam. 1 H302; H318; H412	Acute Tox. Oral 4 Aquatic Longterm 3 Eye Dam. 1 H302; H318; H412	

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Section 3 Composition and Information on Ingredients (Continued)

Ethoxylated lauryl alcohol CAS # 9002-92-0 EINECS # Not available Index # Not available	0.1 - 1	Xn;R22-38-41	Acute Tox. Oral 4 Eye Dam. 1 Skin Irrit. 2 H302; H315; H318	Acute Tox. Oral 4 Eye Dam. 1 Skin Irrit. 2 H302; H315; H318	
Phenol CAS # 108-95-2 EINECS # 203-632-7 Index # 604-001-00-2	0.2 - 0.5	T;R23/24/25-34-48/20/21/22-68 Muta. Cat. 3	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Eye Dam. 1 Muta. 2 STOT RE 2 Skin Corr. 1B H301; H311; H314; H318; H331; H341; H373	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Eye Dam. 1 Muta. 2 STOT RE 2 Skin Corr. 1B H301; H311; H314; H318; H331; H341; H373	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
Peroxidase CAS # 9003-99-0 EINECS # 232-668-6 Index # Not available	< 0.1	Xn;R42/43	Resp. Sens. 1 Skin Sens. 1 H317; H334	Resp. Sens. 1 Skin Sens. 1 H317; H334	15, 8

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. If pain or irritation occurs, obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Exposure may result in irritation of skin and eyes.

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

See Section 11 Toxicological Information for more detailed health information.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Phenol CAS # 108-95-2	5 ppm TWA; 19 mg/m3 TWA; prevent or reduce skin absorption

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
Phenol CAS # 108-95-2	5 ppm TWA; Skin - potential contribution to overall exposure by the cutaneous route

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Phenol CAS # 108-95-2	skin notation

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption
Phenol CAS # 108-95-2	2 ppm TWA; 8 mg/m3 TWA; 4 ppm STEL; 16 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA
Phenol CAS # 108-95-2	Possibility of uptake through the skin; 7.8 mg/m3 TWA; 2 ppm TWA; Possibility of uptake through the skin; 2 ppm TWA; 8 mg/m3 TWA; 4 ppm STEL; 16 mg/m3 STEL

NIOSH

Phenol CAS # 108-95-2	250 ppm IDLH; 5 ppm TWA; 19 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan

Phenol CAS # 108-95-2	5 ppm OEL; 19 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.06 @20°C
Color	Pink	**Solubility**	
Transparency	Clear	**Water**	Not miscible
Odor	Phenol odor	**Organic**	Not determined
pH	6.5 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Phenol 0.0045 ppm odor threshold value		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg
Phenol CAS # 108-95-2	Dermal LD50 Rabbit 630 mg/kg; Oral LD50 Rat 340 mg/kg
Ethoxylated lauryl alcohol CAS # 9002-92-0	Oral LD50 Rat 1 g/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation May cause skin irritation.

Serious eye damage/eye irritation May cause eye irritation.

Respiratory/skin sensitization This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard

Not based on available data.

Other Information

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide
CAS # 26628-22-8

96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

Phenol
CAS # 108-95-2

96 h LC50 Pimephales promelas: 11.9 - 50.5 mg/L -through]; 96 h LC50 Pimephales promelas: 20.5 - 25.6 mg/L [static]; 96 h LC50 Pimephales promelas: 32 mg/L; 96 h LC50 Oncorhynchus mykiss: 5.449 - 6.789 mg/L -through]; 96 h LC50 Oncorhynchus mykiss: 7.5 - 14 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 4.23 - 7.49 mg/L [semi-static]; 96 h LC50 Oncorhynchus mykiss: 5.0 - 12.0 mg/L; 96 h LC50 Lepomis macrochirus: 13.5 mg/L [static]; 96 h LC50 Lepomis macrochirus: 11.9 - 25.3 mg/L -through]; 96 h LC50 Lepomis macrochirus: 11.5 mg/L [semi-static]; 96 h LC50 Poecilia reticulata: 34.09 - 47.64 mg/L [static]; 96 h LC50 Poecilia reticulata: 31 mg/L [semi-static]; 96 h LC50 Brachydanio rerio: 27.8 mg/L; 96 h LC50 Cyprinus carpio: 0.00175 mg/L [semi-static]; 96 h LC50 Oryzias latipes: 33.9 - 43.3 mg/L -through]; 96 h LC50 Oryzias latipes: 23.4 - 36.6 mg/L [static]

Microtox

No information available.

Water Flea

Phenol
CAS # 108-95-2

48 h EC50 Daphnia magna: 4.24 - 10.7 mg/L [Static]; 48 h EC50 Daphnia magna: 10.2 - 15.5 mg/L

Fresh Water Algae

Phenol
CAS # 108-95-2

96 h EC50 Pseudokirchneriella subcapitata: 46.42 mg/L; 96 h EC50 Pseudokirchneriella subcapitata: 0.0188 - 0.1044 mg/L [static]; 72 h EC50 Desmodesmus subspicatus: 187 - 279 mg/L [static]

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313
Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
Phenol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4
Sodium Azide is listed.
Phenol is listed.

California Proposition 65
No ingredients listed.

Massachusetts MSL
Sodium Azide is listed.
Phenol is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.
Phenol is listed.

Pennsylvania RTK
Sodium Azide is listed.
Phenol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide
Phenol
Ethoxylated lauryl alcohol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated part numbers.

Updated section 2, 4, 8, 11, 14.

Hazard Class, hazard statements and risk phrase description from section 3

Muta. Cat. 3 - Mutagen category 3

N - Dangerous for the environment

T - Toxic

T+ - Very toxic

Xn - Harmful

R22 Harmful if swallowed.

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R48/20/21/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

R68 Possible risk of irreversible effects.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R42/43 May cause sensitization by inhalation and skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4

Eye Dam. 1 - Eye Damage Category 1

Muta. 2 - Germ Cell Mutagenicity Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Aquatic Longterm 3 - Aquatic Hazard Long term, Category 3

Resp. Sens. 1 - Respiratory Sensitization Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Irrit. 2 - Skin Irritation Category 2

Skin Sens. 1 - Skin Sensitization Category 1

STOT RE 2 - Target Organ Toxicity Repeated Exposure Category 2

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H302 - Harmful if swallowed.

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Section 16 Other Information (Continued)

H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing dif if inhaled.
H341 - Suspected of causing genetic defects.
H373 - May cause damage to organs through prolonged or repeated exposure.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H412 - Harmful to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6179-75: Version 06
Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14

Product Information

Product Name CK (NAC)

Part Number OSR6179, OSR6279

Additional Product Information

Restricted to professional users.

Components

Description

CK NAC R1-1
CK NAC R1-2
CK NAC R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6179-75 Version 06
Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name CK NAC R1-1

Part Number Component of P/N OSR6179, OSR6279

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.
Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Toxic to Reproductive Category 1

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CK (NAC)
CK NAC R1-1

SAFETY DATA SHEET

Document ID: OSR6179-75 Version 06
Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Toxic to Reproductive Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Imidazole

Pictogram

Signal Word

DANGER

Hazard Statements

H316 Causes mild skin irritation.
H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Imidazole CAS # 288-32-4 EINECS # 206-019-2 Index # Not available	0.5 - < 1	Acute Tox. Oral 4, H302 Repr. 1B, H360 Skin Corr. 1C, H314	Acute Tox. Oral 4, H302 Repr. 1B, H360 Skin Corr. 1C, H314	

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CK (NAC)
CK NAC R1-1

SAFETY DATA SHEET
Document ID: OSR6179-75 Version 06
Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14

Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May damage fertility or the unborn child.

May cause mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3	**Advice for Protective Equipment**	Self-contained breathing apparatus is recommended for in all chemical situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

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Last Revision Date (year/month/day) 2016/06/14

Section 8 Exposure Controls and Personal Protection (Continued)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Not miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	6.2 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	0°C (32°F)	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Imidazole CAS # 288-32-4	Oral LD50 Rat 220 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	May damage fertility or the unborn child.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	
Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	
Imidazole CAS # 288-32-4	48 h EC50 Daphnia magna: 341.5 mg/L
Fresh Water Algae	
Imidazole CAS # 288-32-4	72 h EC50 Desmodesmus subspicatus: 130 mg/L; 96 h EC50 Desmodesmus subspicatus: 82 mg/L

12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.
12.5 Results of PBT and vPvB assessment	
	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6 Other Adverse Effects	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated E-mail address in Sec. 1.3. Updated the concentration range of hazardous ingredient in Sec. 3. Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1 Updated Section 1.	

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Section 16 Other Information (Continued)

Updated Section 4.
Updated Section 8, 11 - 13, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14
Document ID: OSR6179-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Repr. 1B - Toxic to Reproductive Category 1B
H300 - Fatal if swallowed.
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System

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Section 16 Other Information (Continued)

vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Document ID: OSR6179-75 Version 06
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Last Revision Date (year/month/day) 2016/06/14

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name CK NAC R1-2

Part Number Component of P/N OSR6179, OSR6279

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.
Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Toxic to Reproductive Category 1

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Toxic to Reproductive Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Thioglycerol
Imidazole

Pictogram

Signal Word

DANGER

Hazard Statements

H316 Causes mild skin irritation.
H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Thioglycerol CAS # 96-27-5 EINECS # 202-495-0 Index # Not available	1 - 5	Acute Tox. Dermal 3, H311 Acute Tox. Oral 4, H302 Eye Irrit. 2A, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Acute Tox. Dermal 3, H311 Acute Tox. Oral 4, H302 Eye Irrit. 2A, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Imidazole CAS # 288-32-4 EINECS # 206-019-2 Index # Not available	0.5 - < 1	Acute Tox. Oral 4, H302 Repr. 1B, H360 Skin Corr. 1C, H314	Acute Tox. Oral 4, H302 Repr. 1B, H360 Skin Corr. 1C, H314	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May damage fertility or the unborn child.
May cause mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Last Revision Date (year/month/day) 2016/06/14

Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Last Revision Date (year/month/day) 2016/06/14

Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Not miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	6.2 @20°C	**Partition n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	0°C (32°F)	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Imidazole CAS # 288-32-4	Oral LD50 Rat 220 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	May damage fertility or the unborn child.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.

Water Flea

Imidazole CAS # 288-32-4	48 h EC50 Daphnia magna: 341.5 mg/L

Fresh Water Algae

Imidazole CAS # 288-32-4	72 h EC50 Desmodesmus subspicatus: 130 mg/L; 96 h EC50 Desmodesmus subspicatus: 82 mg/L

12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 2, water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

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Section 15 Regulatory Information (Continued)

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated the concentration range of hazardous ingredient in Sec. 3.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated Section 1.
Updated Section 4.
Updated Section 8, 11 - 13, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14
Document ID: OSR6179-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Irrit. 2A - Eye Irritation Category 2A
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
Repr. 1B - Toxic to Reproductive Category 1B
H300 - Fatal if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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CK NAC R1-2

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

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SAFETY DATA SHEET

Document ID: OSR6179-75 Version 06
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Last Revision Date (year/month/day) 2016/06/14

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name CK NAC R2

Part Number Component of P/N OSR6179, OSR6279

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow tint; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.7.9% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard	of Pure Ingredients

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Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

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Section 5 Fire Fighting Measures (Continued)

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.04
Color	Yellow tint	**Solubility**	
Transparency	Clear	**Water**	Fully miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	9.2 @20°C	**Partition n-octanol/water**	Not determined
	Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
	Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

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Last Revision Date (year/month/day) 2016/06/14

Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Update of product hazard and label elements in Sec. 2.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated hazard of pure ingredient in Sec. 3.
Updated Section 4, 8, 11, 12, 15
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/05/07
Last Revision Date (year/month/day) 2016/06/14
Document ID: OSR6179-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1

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Section 16 Other Information (Continued)

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER
Cleaning Solution

SAFETY DATA SHEET

Document ID: 66039-75 Version 03
Revision Date (year/month/day) 2020/05/21
Last Revision Date (year/month/day) 2019/04/01

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name **Cleaning Solution**

Part Number 66039

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow; Clear; Liquid; Chlorine odor

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1
Aquatic Hazard Acute, Category 1
Aquatic Hazard Long term, Category 2

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1
Aquatic Hazard Acute, Category 1
Aquatic Hazard Long term, Category 2

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Cleaning Solution

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Document ID: 66039-75 Version 03
Revision Date (year/month/day) 2020/05/21
Last Revision Date (year/month/day) 2019/04/01

Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hypochlorite

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
EUH031 Contact with acids liberates toxic gas.

Precautionary Statements

P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Hypochlorite CAS # 7681-52-9 EINECS # 231-668-3 Index # 017-011-00-1	5 - 10	Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=10 M-factor Chronic=1 Skin Corr. 1B, H314	Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

Contact with acids liberates toxic gas.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3	**Advice for Protective Equipment**	Self-contained breathing apparatus is recommended for in all chemical situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1	**Personal precautions, protective equipment and emergency procedures**	
	Personal Precautions	Wear protective gloves, protective clothing and tightly sealed eye/face protection.
6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	Use good laboratory procedures; avoid eye and skin contact.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	None established
	DFG MAK	None established
	Ireland	None established
	IOELVs	None established
	NIOSH	None established
	Japan	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Sweden (AFS 2015:7 and amendments)

None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.0946 @20°C
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Chlorine odor	**Organic**	Not determined
pH	>11.5	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not determined
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hypochlorite
CAS # 7681-52-9 Dermal LD50 Rabbit >10000 mg/kg; Oral LD50 Rat 8.91 g/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Contact may cause severe skin burns.

Serious eye damage/eye irritation Contact may cause serious eye damage.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard	Not based on available data.
Other Information	Contact with acids liberates toxic gas.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hypochlorite CAS # 7681-52-9	96 h LC50 Pimephales promelas: 0.06 - 0.11 mg/L -through]; 96 h LC50 Pimephales promelas: 4.5 - 7.6 mg/L [static]; 96 h LC50 Lepomis macrochirus: 0.4 - 0.8 mg/L [static]; 96 h LC50 Lepomis macrochirus: 0.28 - 1 mg/L -through]; 96 h LC50 Oncorhynchus mykiss: 0.05 - 0.771 mg/L -through]; 96 h LC50 Oncorhynchus mykiss: 0.03 - <0.19 mg/L [semi-static]; 96 h LC50 Oncorhynchus mykiss: 0.18 - 0.22 mg/L [static]
Microtox	No information available.

Water Flea

Sodium Hypochlorite CAS # 7681-52-9	48 h EC50 Daphnia magna: 0.033 - 0.044 mg/L [Static]
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2	**Additional information**	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1791	1791	1791	1791	PIN - 1791
14.2	Shipping Name	Hypochlorite Solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C9	Not applicable
14.4	Packing Group	III	III	III	III	III
	Special Provisions	A3, A803	Not applicable	N34	Not applicable	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	P	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7681-52-9 Sodium Hypochlorite

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7681-52-9 Sodium Hypochlorite

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7681-52-9 Sodium Hypochlorite

Pennsylvania Right To Know (RTK) List

CAS # 7681-52-9 Sodium Hypochlorite

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 2, water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Update of product hazard and label elements in Sec. 2.
Updated hazard of pure ingredient in Sec. 3.
Updated Section 4, 7, 11, 16.

Document version and issue/revision date

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Last Revision Date (year/month/day) 2019/04/01

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Section 16 Other Information (Continued)

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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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THE CLOROX COMPANY

SAFETY DATA SHEET

Clorox® Bleach Regular

According to Regulation (EC) No 1907/2006, Annex II, as amended by Regulation (EU) No 453/2010

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name Clorox® Bleach Regular

Product number CX0030HU, CX0033HU, CX0035HU

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Bleach

Uses advised against No specific uses advised against are identified.

1.3. Details of the supplier of the safety data sheet

Supplier

CBee (Europe) Ltd.
Eton House
2nd Floor
18 - 24 Paradise Road
Richmond
TW9 1SE
UK
Tel: + 44 (0) 208 614 7120
Fax: + 44 (0) 208 940 2040
consumerservices@clorox.co.uk

1.4. Emergency telephone number

Emergency telephone

+44 (0) 208 614 7120
Monday - Thursday:- 09:00 - 17:30
Friday:- 09:00 - 17:00

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification

Physical hazards
Not Classified

Health hazards
Skin Irrit. 2 - H315 Eye Irrit. 2 - H319

Environmental hazards
Aquatic Acute 1 - H400

Classification (67/548/EEC or 1999/45/EC)
Xi; R36/38. N; R50

2.2. Label elements

Pictogram

Signal word Warning

Clorox® Bleach Regular

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.

Precautionary statements

P102 Keep out of reach of children.
P264 Wash contaminated skin thoroughly after handling.
P280 Wear eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents/container in accordance with national regulations.

Supplemental label information

EUH206 Warning! Do not use together with other products. May release dangerous gases (chlorine).

Contains Sodium hypochlorite, solution 4.8 % Cl active

Detergent labelling < 5% disinfectants

Supplementary precautionary statements

P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.
P391 Collect spillage.

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Sodium hypochlorite, solution ... % Cl active	**4.8%**
CAS number: 7681-52-9 **EC number:** 231-668-3	
M factor (Acute) = 10	
Classification	**Classification (67/548/EEC or 1999/45/EC)**
Skin Corr. 1B - H314	C; R34. N; R50. R31
Eye Dam. 1 - H318	
Aquatic Acute 1 - H400	
sodium hydroxide	**0.025 - <0.25%**
CAS number: 1310-73-2 **EC number:** 215-185-5	
Classification	**Classification (67/548/EEC or 1999/45/EC)**
Skin Corr. 1A - H314	C; R35
Eye Dam. 1 - H318	

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.

Ingestion

Rinse mouth thoroughly with water. Give plenty of water to drink. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.

Skin contact

Wash skin thoroughly with soap and water.

Eye contact

Remove any contact lenses and open eyelids wide apart. Continue to rinse.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation

Irritation of nose, throat and airway.

Ingestion

May cause discomfort if swallowed.

Skin contact

Skin irritation.

Eye contact

Irritation of eyes and mucous membranes. Prolonged contact may cause redness and/or tearing.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor

The severity of the symptoms described will vary dependent on the concentration and the length of exposure.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog. Use fire-extinguishing media suitable for the surrounding fire.

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products

Thermal decomposition or combustion products may include the following substances: Oxides of carbon. Toxic gases or vapours.

5.3. Advice for firefighters

Special protective equipment for firefighters

Use protective equipment appropriate for surrounding materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions

Contain spillage with sand, earth or other suitable non-combustible material. Avoid discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

Neutralise spilled material with diluted hydrochloric acid. Absorb in vermiculite, dry sand or earth and place into containers. Containers with collected spillage must be properly labelled with correct contents and hazard symbol.

6.4. Reference to other sections

Reference to other sections

See Section 11 for additional information on health hazards. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions

Read and follow manufacturer's recommendations.

Advice on general occupational hygiene

Avoid contact with eyes and prolonged skin contact.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions

Store in a cool and well-ventilated place.

7.3. Specific end use(s)

Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

sodium hydroxide

Short-term exposure limit (15-minute): WEL 2 mg/m3

WEL = Workplace Exposure Limit

8.2. Exposure controls

Eye/face protection

Wear chemical splash goggles.

Hygiene measures

No specific hygiene procedures recommended but good personal hygiene practices should always be observed when working with chemical products.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance

Clear liquid.

Colour

Colourless.

Odour

Chlorine.

Odour threshold

Not determined.

pH

pH (concentrated solution): 12.5

Melting point

Not relevant.

Initial boiling point and range

Not determined.

Flash point

Not determined.

Evaporation rate

Not determined.

Evaporation factor
Not determined.

Flammability (solid, gas)
Not relevant.

Upper/lower flammability or explosive limits
Not relevant.

Vapour pressure
Not determined.

Vapour density
Not relevant.

Relative density
1.05

Bulk density
Not determined.

Solubility(ies)
Soluble in water.

Partition coefficient
Not determined.

Auto-ignition temperature
Not relevant.

Decomposition Temperature
Not relevant.

Viscosity
Not determined.

Explosive properties
Not considered to be explosive.

Oxidising properties
The mixture itself has not been tested but none of the ingredient substances meet the criteria for classification as oxidising.

9.2. Other information

Other information
No information required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Acids. Alkalis. Oxidising materials.

10.2. Chemical stability

Stability
Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Will not polymerise.

10.4. Conditions to avoid

Avoid excessive heat for prolonged periods of time.

10.5. Incompatible materials

Materials to avoid
Avoid contact with strong oxidising agents. Acids.

Clorox® Bleach Regular

10.6. Hazardous decomposition products

None at ambient temperatures. Thermal decomposition or combustion products may include the following substances: Oxides of carbon. Oxides of nitrogen. Chlorides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

Based on available data the classification criteria are not met.

Acute toxicity - dermal

Based on available data the classification criteria are not met.

Acute toxicity - inhalation

Based on available data the classification criteria are not met.

Skin corrosion/irritation

Animal data

Dose: 0.5 ml, Rabbit, Skin Irrit. 2 - H315 Causes skin irritation.

Serious eye damage/irritation

Dose: 0.1 ml, 1 second, Rabbit Eye Irrit. 2 - H319 May cause severe eye irritation.

Respiratory sensitisation

Based on available data the classification criteria are not met.

Skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity - in vitro

Based on available data the classification criteria are not met.

Genotoxicity - in vivo

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Reproductive toxicity - fertility

Based on available data the classification criteria are not met.

Reproductive toxicity - development

Based on available data the classification criteria are not met.

Specific target organ toxicity - single exposure

STOT - single exposure

Based on available data the classification criteria are not met.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Not anticipated to present an aspiration hazard, based on chemical structure.

Toxicological information on ingredients.

Sodium hypochlorite, solution ... % Cl active

Acute toxicity - oral

Acute toxicity oral (LD50 mg/kg)

8,830.0

Species

Clorox® Bleach Regular

Rat

REACH dossier information. Based on available data the classification criteria are not met.

ATE oral (mg/kg)
8,830.0

Acute toxicity - dermal

Acute toxicity dermal (LD50 mg/kg)
20000.0

Species
Rabbit

REACH dossier information. Based on available data the classification criteria are not met.

ATE dermal (mg/kg)
20000.0

Acute toxicity - inhalation

Based on available data the classification criteria are not met.

Skin corrosion/irritation

Animal data
Dose: 5.3%, 4 hours, Rabbit Primary dermal irritation index: 1.2 Dose: 0.5 ml (12.5%), 24 hours, Rabbit Erythema/eschar score: Well defined erythema (2). Oedema score: Very slight oedema - barely perceptible (1). REACH dossier information. Corrosive to skin.

Serious eye damage/irritation
Dose: 0.1 g, 1 second, Rabbit REACH dossier information. Corrosivity to eyes is assumed.

Skin sensitisation
Buehler test - Guinea pig: Not sensitising. REACH dossier information.

Germ cell mutagenicity

Genotoxicity - in vitro
Chromosome aberration: Negative. REACH dossier information.

Genotoxicity - in vivo
Chromosome aberration: Negative. REACH dossier information.

Carcinogenicity
NOAEL > 13.75 mg/kg/day, Oral, Rat REACH dossier information.

IARC carcinogenicity
IARC Group 3 Not classifiable as to its carcinogenicity to humans.

Reproductive toxicity

Reproductive toxicity - fertility
One-generation study - NOAEL > 5 mg/kg/day, Oral, Rat P REACH dossier information.

Reproductive toxicity - development
Teratogenicity: - NOAEL: >=5.7 mg/kg/day, Oral, Rat REACH dossier information.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure
LOAEL 100 mg/kg/day, Oral, Rat REACH dossier information.

Aspiration hazard
Not anticipated to present an aspiration hazard, based on chemical structure.

Clorox® Bleach Regular

sodium hydroxide

Skin corrosion/irritation

Animal data

Skin Corr. 1A - H314

Serious eye damage/irritation

Dose: 0.1 ml (2%), 1 second, Rabbit REACH dossier information.

Skin sensitisation

Patch test - Human: Not sensitising. REACH dossier information.

Aspiration hazard

Not anticipated to present an aspiration hazard, based on chemical structure.

SECTION 12: Ecological Information

12.1. Toxicity

Aquatic Acute 1 - H400 Very toxic to aquatic life.

Ecological information on ingredients.

Sodium hypochlorite, solution ... % Cl active

Acute aquatic toxicity

LE(C)$_{50}$

0.01 < L(E)C50 ≤ 0.1

M factor (Acute)

10

Acute toxicity - fish

LC_{50}, 96 hours: 0.032 mg/l, Oncorhynchus kisutch (Coho salmon) REACH dossier information.

Acute toxicity - aquatic invertebrates

EC_{50}, 48 hours: 0.141 mg/l, Daphnia magna REACH dossier information.

Acute toxicity - microorganisms

EC_{50}, 3 hours: > 3 mg/l, Activated sludge REACH dossier information.

Acute toxicity - terrestrial

NOEC, 10 days: 200 mg/l, Coturnix coturnix japonica (Japanese quail) REACH dossier information.

Chronic toxicity - fish early life stage

NOEC, 28 days: 0.04 mg/l, Menidia peninsulae (Tidewater silverside) REACH dossier information.

Chronic toxicity - aquatic invertebrates

NOEC, 15 days: 0.007 mg/l, Freshwater invertebrates REACH dossier information.

sodium hydroxide

Acute toxicity - fish

LC_{50}, 48 hours: 189 mg/l, Leuciscus idus (Golden orfe)

Acute toxicity - aquatic invertebrates

EC_{50}, 48 hours: 40.4 mg/l, Ceriodaphnia REACH dossier information.

12.2. Persistence and degradability

Persistence and degradability

The surfactant(s) contained in this product complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them at their direct request, or at the request of a detergent manufacturer.

Ecological information on ingredients.

Sodium hypochlorite, solution ... % Cl active

Phototransformation

Air - DT_{50} : 114.6 days Estimated value. Water - DT_{50} : 12 minutes REACH dossier information.

12.3. Bioaccumulative potential

No data available on bioaccumulation.

Partition coefficient

Not determined.

Ecological information on ingredients.

Sodium hypochlorite, solution ... % Cl active

Partition coefficient

log Pow: -3.42 Estimated value. REACH dossier information.

sodium hydroxide

The product is not bioaccumulating.

12.4. Mobility in soil

Mobility

The product is soluble in water.

Ecological information on ingredients.

Sodium hypochlorite, solution ... % Cl active

Henry's law constant

0.076 @ 20°C Estimated value. REACH dossier information.

Surface tension

82.4 mN/m @ 20°C REACH dossier information.

12.5. Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6. Other adverse effects

Not relevant.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General information

When handling waste, the safety precautions applying to handling of the product should be considered. Dispose of waste product or used containers in accordance with local regulations

Disposal methods

Avoid the spillage or runoff entering drains, sewers or watercourses. Neutralise waste with diluted hydrochloric acid.

SECTION 14: Transport information

14.1. UN number

UN No. (ADR/RID)	3082
UN No. (IMDG)	3082
UN No. (ICAO)	3082
UN No. (ADN)	3082

14.2. UN proper shipping name

Proper shipping name (ADR/RID)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SODIUM HYPOCHLORITE)

Clorox® Bleach Regular

Proper shipping name (IMDG)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SODIUM HYPOCHLORITE)
Proper shipping name (ICAO)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SODIUM HYPOCHLORITE)
Proper shipping name (ADN)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SODIUM HYPOCHLORITE)

14.3. Transport hazard class(es)

ADR/RID class	9
ADR/RID classification code	M6
ADR/RID label	9
IMDG class	9
ICAO class/division	9
ADN class	9

Transport labels

14.4. Packing group

ADR/RID packing group	III
IMDG packing group	III
ICAO packing group	III
ADN packing group	III

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

Yes.

14.6. Special precautions for user

EmS	F-A, S-F
ADR transport category	3
Emergency Action Code	•3Z
Hazard Identification Number (ADR/RID)	90
Tunnel restriction code	(E)

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

EH40/2005 Workplace exposure limits.

EU legislation

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (as amended)

Clorox® Bleach Regular

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008

Aquatic Acute 1 - H400: Calculation method. Eye Irrit. 2 - H319, Skin Irrit. 2 - H315: On basis of test data.

Revision comments

Classification according to CLP Annex I.

Revision date	01/04/2014
Revision	7
Supersedes date	01/12/2013
SDS number	25

Risk phrases in full

R31 Contact with acids liberates toxic gas.
R34 Causes burns.
R35 Causes severe burns.
R36/38 Irritating to eyes and skin.
R50 Very toxic to aquatic organisms.

Hazard statements in full

H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.

Disclaimer

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SAFETY DATA SHEET

Issuing Date January 5, 2015 **Revision Date** June 12, 2015 **Revision Number** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name **Clorox® Regular-Bleach$_1$**

Other means of identification

EPA Registration Number 5813-100

Recommended use of the chemical and restrictions on use

Recommended use Household disinfecting, sanitizing, and laundry bleach

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Address
The Clorox Company
1221 Broadway
Oakland, CA 94612

Phone: 1-510-271-7000

Emergency telephone number

Emergency Phone Numbers For Medical Emergencies, call: 1-800-446-1014
For Transportation Emergencies, call Chemtrec: 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Skin corrosion/irritation	Category 1
Serious eye damage/eye irritation	Category 1

GHS Label elements, including precautionary statements

Emergency Overview

Signal word **Danger**

Hazard Statements
Causes severe skin burns and eye damage
Causes serious eye damage

Appearance Clear, pale yellow **Physical State** Thin liquid **Odor** Bleach

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling.
Wear protective gloves, protective clothing, face protection, and eye protection such as safety glasses.

Precautionary Statements - Response
Immediately call a poison center or doctor.
If swallowed: Rinse mouth. Do NOT induce vomiting.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
Wash contaminated clothing before reuse.
If inhaled: Remove person to fresh air and keep comfortable for breathing.
Specific treatment (see supplemental first aid instructions on this label).
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Precautionary Statements - Storage
Store locked up.

Precautionary Statements - Disposal
Dispose of contents in accordance with all applicable federal, state, and local regulations.

Hazards not otherwise classified (HNOC)
Although not expected, heart conditions or chronic respiratory problems such as asthma, chronic bronchitis, or obstructive lung disease may be aggravated by exposure to high concentrations of vapor or mist.

Product contains a strong oxidizer. Always flush drains before and after use.

Unknown Toxicity
Not applicable.

Other information
Very toxic to aquatic life with long lasting effects.

Interactions with Other Chemicals
Reacts with other household chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia to produce hazardous irritating gases, such as chlorine and other chlorinated compounds.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade Secret
Sodium hypochlorite	7681-52-9	5 - 10	*

* The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General Advice Call a poison control center or doctor immediately for treatment advice. Show this safety data sheet to the doctor in attendance.

Eye Contact Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Skin Contact Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Inhalation Move to fresh air. If breathing is affected, call a doctor.

Ingestion Have person sip a glassful of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.

Protection of First-aiders Avoid contact with skin, eyes, and clothing. Use personal protective equipment as required. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Burning of eyes and skin.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically. Probable mucosal damage may contraindicate the use of gastric lavage.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media
CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical
This product causes burns to eyes, skin, and mucous membranes. Thermal decomposition can release sodium chlorate and irritating gases and vapors.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with eyes, skin, and clothing. Ensure adequate ventilation. Use personal protective equipment as required. For spills of multiple products, responders should evaluate the MSDSs of the products for incompatibility with sodium hypochlorite. Breathing protection should be worn in enclosed and/or poorly-ventilated areas until hazard assessment is complete.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental Precautions This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not allow product to enter storm drains, lakes, or streams. See Section 12 for ecological Information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Absorb and containerize. Wash residual down to sanitary sewer. Contact the sanitary treatment facility in advance to assure ability to process washed-down material.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes, and clothing. Do not eat, drink, or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Store away from children. Reclose cap tightly after each use. Store this product upright in a cool, dry area, away from direct sunlight and heat to avoid deterioration. Do not contaminate food or feed by storage of this product.

Incompatible Products Toilet bowl cleaners, rust removers, acids, and products containing ammonia.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hypochlorite 7681-52-9	None	None	None

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. NIOSH IDLH: Immediately Dangerous to Life or Health.

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection If splashes are likely to occur: Wear safety glasses with side shields (or goggles) or face shield.

Skin and Body Protection Wear rubber or neoprene gloves and protective clothing such as long-sleeved shirt.

Respiratory Protection If irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Wash hands after direct contact. Do not wear product-contaminated clothing for prolonged periods. Remove and wash contaminated clothing before re-use. Do not eat, drink, or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical State	Thin liquid		
Appearance	Clear	**Odor**	Bleach
Color	Pale yellow	**Odor Threshold**	No information available

Property	**Values**	**Remarks/ Method**
pH	~12	None known
Melting/freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	Not flammable	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
Upper flammability limit	No data available	None known
Lower flammability limit	No data available	None known
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	~1.1	None known
Water Solubility	Soluble	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive Properties	Not explosive	
Oxidizing Properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	No data available

10. STABILITY AND REACTIVITY

Reactivity
Reacts with other household chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia to produce hazardous irritating gases, such as chlorine and other chlorinated compounds.

Chemical stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
None known based on information supplied.

Incompatible materials
Toilet bowl cleaners, rust removers, acids, and products containing ammonia.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information .

Inhalation Exposure to vapor or mist may irritate respiratory tract and cause coughing. Inhalation of high concentrations may cause pulmonary edema.

Eye Contact Corrosive. May cause severe damage to eyes.

Skin Contact May cause severe irritation to skin. Prolonged contact may cause burns to skin.

Ingestion Ingestion may cause burns to gastrointestinal tract and respiratory tract, nausea, vomiting, and diarrhea.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hypochlorite 7681-52-9	8200 mg/kg (Rat)	>10000 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms May cause redness and tearing of the eyes. May cause burns to eyes. May cause redness or burns to skin. Inhalation may cause coughing.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Sodium hypochlorite 7681-52-9	-	Group 3	-	-

IARC (International Agency for Research on Cancer)
Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive Toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.
Chronic Toxicity Carcinogenic potential is unknown.
Target Organ Effects Respiratory system, eyes, skin, gastrointestinal tract (GI).

Aspiration Hazard No information available.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)
54 g/kg
ATEmix (inhalation-dust/mist)
58 mg/L

12. ECOLOGICAL INFORMATION

Ecotoxicity
Very toxic to aquatic life with long lasting effects.

This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not allow product to enter storm drains, lakes, or streams.

Persistence and Degradability
No information available.

Bioaccumulation
No information available.

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods
Dispose of in accordance with all applicable federal, state, and local regulations. Do not contaminate food or feed by disposal of this product.

Contaminated Packaging
Do not reuse empty containers. Dispose of in accordance with all applicable federal, state, and local regulations.

14. TRANSPORT INFORMATION

DOT	Not restricted.
TDG	Not restricted for road or rail.
ICAO	Not restricted, as per Special Provision A197, Environmentally Hazardous Substance exception.
IATA	Not restricted, as per Special Provision A197, Environmentally Hazardous Substance exception.
IMDG/IMO	Not restricted, as per IMDG Code 2.10.2.7, Marine Pollutant exception.

15. REGULATORY INFORMATION

Chemical Inventories

TSCA	All components of this product are either on the TSCA 8(b) Inventory or otherwise exempt from listing.
DSL/NDSL	All components are on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hypochlorite 7681-52-9	100 lb			X

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium hypochlorite 7681-52-9	100 lb	-	RQ 100 lb final RQ RQ 45.4 kg final RQ

EPA Statement
This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

> **DANGER: CORROSIVE.** Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear and rubber gloves when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Avoid breathing vapors and use only in a well-ventilated area.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Sodium hypochlorite 7681-52-9	X	X	X	X	
Sodium chlorate 7775-09-9	X	X	X		

International Regulations

Canada
WHMIS Hazard Class
E - Corrosive material

16. OTHER INFORMATION

NFPA	**Health Hazard**	3	**Flammability**	0	**Instability**	0	**Physical and Chemical Hazards** -
HMIS	**Health Hazard**	3	**Flammability**	0	**Physical Hazard**	0	**Personal Protection** B

Prepared By
Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Revision Date June 12, 2015

Revision Note Revision Section 14.

Reference 1096036/164964.159

General Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

SAFETY DATA SHEET

Issuing Date January 5, 2015 **Revision Date** October 19, 2015 **Revision Number** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name **Clorox® Clean-Up® Cleaner + Bleach$_1$ - Original**

Other means of identification

EPA Registration Number 5813-21

Recommended use of the chemical and restrictions on use

Recommended use Disinfecting bleach spray cleaner

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Address
The Clorox Company
1221 Broadway
Oakland, CA 94612

Phone: 1-510-271-7000

Emergency telephone number

Emergency Phone Numbers For Medical Emergencies, call: 1-800-446-1014
For Transportation Emergencies, call Chemtrec: 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Skin corrosion/irritation	Category 3
Serious eye damage/eye irritation	Category 2A

GHS Label elements, including precautionary statements

Emergency Overview

Signal word **Warning**

Hazard Statements
Causes mild skin irritation
Causes serious eye irritation

Appearance Clear, pale yellow **Physical State** Thin liquid **Odor** Citrus, herbaceous, bleach

Precautionary Statements - Prevention
Wash hands and any exposed skin thoroughly after handling.
Wear eye protection/face protection such as safety glasses.

Precautionary Statements - Response
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
If skin irritation occurs: Get medical advice/attention.

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
None

Hazards not otherwise classified (HNOC)
The following medical conditions may be aggravated by exposure to high concentrations of vapor or mist: heart conditions or chronic respiratory problems such as asthma, emphysema, or obstructive lung disease.

Unknown Toxicity
0.12% of the mixture consists of ingredient(s) of unknown toxicity

Other information
Toxic to aquatic life with long lasting effects

Interactions with Other Chemicals
Reacts with other household chemicals such as products containing ammonia, toilet bowl cleaners, rust removers, or acids to produce hazardous gases, such as chlorine and other chlorinated compounds.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade Secret
Sodium hypochlorite	7681-52-9	1 - 5	*
Sodium hydroxide	1310-73-2	0.1 - 1	*

* The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General Advice Show this safety data sheet to the doctor in attendance.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin Contact Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. If irritation develops, call a doctor.

Inhalation Move to fresh air. If breathing is affected, call a doctor.

Ingestion Call a poison control center or doctor immediately. Have person sip a glassful of water if able to swallow. DO NOT induce vomiting unless told to do so by a poison control center or doctor.

Protection of First-aiders Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Stinging and irritation of eyes.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media
CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical
No information available.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with eyes, skin, and clothing. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental Precautions See Section 12 for ecological Information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Absorb and containerize. Wash residual down to sanitary sewer. Contact the sanitary treatment facility in advance to assure ability to process washed-down material.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Products containing ammonia, toilet bowl cleaners, rust removers, or acids.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hypochlorite 7681-52-9	None	None	None
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m^3	TWA: 2 mg/m^3	IDLH: 10 mg/m^3 Ceiling: 2 mg/m^3

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. NIOSH IDLH: Immediately Dangerous to Life or Health.

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection	If splashes are likely to occur: Wear safety glasses with side shields (or goggles). None required for consumer use.
Skin and Body Protection	Wear protective gloves and protective clothing.
Respiratory Protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene Measures	Remove and wash contaminated clothing before re-use. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical State	Thin liquid		
Appearance	Clear	**Odor**	Citrus, herbaceous, bleach
Color	Pale yellow	**Odor Threshold**	No information available

Property	**Values**	**Remarks/ Method**
pH	12.4 - 12.8	None known
Melting/freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	Not flammable	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
Upper flammability limit	No data available	None known
Lower flammability limit	No data available	None known
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	~1.03	None known
Water Solubility	Soluble in water	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive Properties	Not explosive	
Oxidizing Properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	No data available

10. STABILITY AND REACTIVITY

Reactivity
Reacts with other household chemicals such as products containing ammonia, toilet bowl cleaners, rust removers, or acids to produce hazardous gases, such as chlorine and other chlorinated compounds.

Chemical stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
None known based on information supplied.

Incompatible materials
Products containing ammonia, toilet bowl cleaners, rust removers, vinegar, or acids.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information .

Inhalation Exposure to vapor or mist may irritate respiratory tract.

Eye Contact May cause eye irritation.

Skin Contact Prolonged contact may cause irritation.

Ingestion Ingestion may cause irritation to mucous membranes and gastrointestinal tract, nausea, vomiting, and diarrhea.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hypochlorite 7681-52-9	8200 mg/kg (Rat)	>10000 mg/kg (Rabbit)	-
Sodium hydroxide 1310-73-2	-	1350 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms May cause redness and tearing of the eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Sodium hypochlorite 7681-52-9	-	Group 3	-	-

IARC (International Agency for Research on Cancer)
Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive Toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.
Chronic Toxicity Carcinogenic potential is unknown.
Target Organ Effects Respiratory system, eyes, skin, gastrointestinal tract (GI).

Aspiration Hazard No information available.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document
Not applicable.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Toxic to aquatic life with long lasting effects.

Persistence and Degradability
No information available.

Bioaccumulation
No information available.

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods
Dispose of in accordance with all applicable federal, state, and local regulations.

Contaminated Packaging
Do not reuse empty containers. Dispose of in accordance with all applicable federal, state, and local regulations.

14. TRANSPORT INFORMATION

DOT Not restricted.

TDG Not restricted for road or rail.

ICAO Not restricted, as per Special Provision A197, Environmentally Hazardous Substance exception.

IATA Not restricted, as per Special Provision A197, Environmentally Hazardous Substance exception.

IMDG/IMO Not restricted, as per IMDG Code 2.10.2.7, Marine Pollutant exception.

15. REGULATORY INFORMATION

Chemical Inventories

TSCA	All components of this product are either on the TSCA 8(b) Inventory or otherwise exempt from listing.
DSL/NDSL	All components are on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hypochlorite 7681-52-9	100 lb			X
Sodium hydroxide 1310-73-2	1000 lb			X

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium hypochlorite 7681-52-9	100 lb	-	RQ 100 lb final RQ RQ 45.4 kg final RQ
Sodium hydroxide 1310-73-2	1000 lb	-	RQ 1000 lb final RQ RQ 454 kg final RQ

EPA Statement
This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

> **WARNING: EYE AND SKIN IRRITANT**. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. For sensitive skin or prolonged use, wear gloves. Vapors may irritate. Avoid prolonged breathing of vapors. Use only in well ventilated areas. **Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease.**

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Sodium hypochlorite 7681-52-9	X	X	X	X	
Sodium hydroxide 1310-73-2	X	X	X	X	

International Regulations

Canada
WHMIS Hazard Class
D2B - Toxic materials

16. OTHER INFORMATION

NFPA	**Health Hazard**	2	**Flammability** 0	**Instability** 0		**Physical and Chemical Hazards**	-
HMIS	**Health Hazard**	2	**Flammability** 0	**Physical Hazard** 0		**Personal Protection**	B

Prepared By
Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Revision Date October 19, 2015

Revision Note Revisions Sections 2, 8, and 14.

Reference 1086795/50546003.004

General Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 446450-75 Rev. AJ
Revised (year/month/day) 2015/05/05

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Complement C3 Reagent

Part Number 446450

Series Name IMMAGE Immunochemistry Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless to yellow; Transparent; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.005 @20°C
Color	Colorless to yellow	**Solubility**	
Transparency	Transparent	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.5 - 7.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 446490-75 Rev. AK
Revised (year/month/day) 2015/05/05

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Complement C4 Reagent

Part Number 446490

Series Name IMMAGE Immunochemistry Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless to yellow; Transparent; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

	Flammable Properties	Nonflammable aqueous solution.
5.1	**Extinguishing Media**	In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3	**Advice for fire fighters**	
	Protective Equipment	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

	Personal Precautions	This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures. Wear protective gloves, protective clothing and eye/face protection.
6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

	Spill and Leak Procedures	As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless to yellow	**Solubility**	
Transparency	Transparent	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.5 - 7.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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MCKESSON SAFETY DATA SHEET SDS DATE: 11.19.15

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME: CONSULT® hCG Dipstick (5000), CONSULT® hCG Urine Cassette Test (5001), CONSULT® hCG Combo cassette test (5002),

MFR #: 5000 (Dipstick); 5001 (Cassette); 5002 (Combo Cassette)

DISTRIBUTEDBY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908 Monday-Friday 8:00a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company) Day or Night

PRODUCT DESCRIPTION/IDENTIFIED USES: *In vitro* diagnostic reagent. For professional use only.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)	Eye Irrit. 2
Hazard statement(s)	H319: Causes serious eye irritation.
Directive 67/548/EEC & Directive 1999/45/EC	Not classified as dangerous for supply/use.
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) /GHS	Eye Irrit. 2
Hazard statement(s)	Causes serious eye irritation.

2.2 Label elements — No measures required. The product is placed on the market in the form of an article, which contains insignificant quantities of hazardous chemicals that are not intended to be released from the device.

2.3 Other hazards — None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Description: In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:
EC Classification No. 1272/2008 / GHS

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	Classification code: Hazard statement(s)
Sodium carbonate	1 - 2	207-838-8	497-19-8	Eye Irrit. 2; H319
Triton X100*	1 - 2	-	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411
Sodium azide**	< 0.1	247-852-1	26628-22-8	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	EC Classification and Risk Phrases

Sodium carbonate	1 - 2	207-838-8	497-19-8	Xi; R36
Triton X100*	1 - 2	-	9002-93-1	Xn; R22-41-51/53
Sodium azide**	< 0.1	247-852-1	26628-22-8	T+, N; R28-32-50/53

* candidate substance of very high concern (SVHC)

** Substance with a community exposure limit

3.3 Additional Information

For full text of R/H phrases see section 16.
Each device is packaged in a foil pouch.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information: The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

Inhalation: Supply fresh air; consult doctor in case of complaint.

Skin Contact: Wash skin with soap and water.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Ingestion: Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

None.

4.3 Indication of the immediate medical attention and special treatment needed

None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes, Carbon oxides (COx), nitrogen oxides (NOx).

5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Collect material and dispose of as waste according to Section 13.

6.4 Reference to other sections

8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.

Clean work areas with hypochlorite or other disinfecting agent.

7.2 Conditions for safe storage, including any incompatibilities — Store in the original container at 2 to 30°C.

7.3 Specific end use(s) — Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits — EU IOELV / UK WEL / Irl OELV

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note:
Sodium Azide	26628-22-8		0.1		0.3	Sk

Sk - Can be absorbed through skin.

8.2 Exposure controls

8.2.1 Appropriate engineering controls — Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection — Safety glasses recommended. (EN166)

Hand protection — Disposable gloves. (EN374).

Material of gloves: — Latex / natural rubber, Nitrile rubber.

Penetration time of glove material: — Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection — Laboratory coat.

Respiratory protection — Not normally required.

8.2.3 Environmental Exposure Controls — No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Laminated test strip, which may be housed in a plastic holder.
Colour	Variable depending on product.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not determined.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (mm Hg)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not applicable.
Solubility (Water)	Not determined.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising

9.2 Other information — Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1	**Reactivity**	None known.
10.2	**Chemical stability**	The product is stable in accordance with therecommended storage conditions.
10.3	**Possibility of hazardous reactions**	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4	**Conditions to avoid**	None.
10.5	**Incompatible materials**	None.
10.6	**Hazardous Decomposition Product(s)**	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Causes serious eye irritation.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are not met.
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2	**Persistence and degradability**	The device contains plastic and other components that are not readily degradable.
12.3	**Bioaccumulative potential**	None anticipated.
12.4	**Mobility in soil**	The product is predicted to have low mobility in soil.
12.5	**Results of PBT and vPvB assessment**	Not applicable.
12.6	**Other adverse effects**	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.
Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/oran

	approved waste-disposal company for information.
European waste catalogue:	18 01 03.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	**UN number**	Not applicable
14.2	**UN Proper Shipping Name**	Not applicable
14.3	**Transport hazard class(es)**	Not classified as dangerous for transport.
14.4	**Packing Group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special precautions for user**	Not applicable
14.7	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	**Safety, health and environmental regulations/legislation specific for the substance or mixture**	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA:	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	Sodium azide (trace).
	Section 313 (specific toxic chemical listings):	Sodium azide (trace).
15.2	**Chemical Safety Assessment**	Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT	Specific Target Organ Toxicity
STEL	Short Term Exposure Limit
LTEL	Long Term Exposure limit
TWA	Time Weighted Average

Classification code:

Acute Tox. 4	Acute toxicity; Category 4
Acute Tox. 2	Acute toxicity: Category 2
Eye Dam. 1	Eye damage; Category 1
Eye Irrit. 2	Eye Irritation: Category 2
Aquatic Acute 1	Hazardous to the aquatic environment Acute: Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment Chronic: Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment Chronic: Category 2

Xi	rritant
Xn	Harmful.
T+	Very toxic.
N	Dangerous for theenvironment.

Hazard statement(s)

H300: Fatal if swallowed.
H302: Harmful ifswallowed.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lastingeffects.
H411: Toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxicgas.

Risk Phrases

R22: Harmful if swallowed.
R28: Very toxic ifswallowed.
R32: Contact with acids liberates very toxic gas.
R36: Irritating to eyes.
R41: Risk of serious damage toeyes.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

References:

Raw material safety data sheets.

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1 of 2 SDS for CONSULT H.PYLORI CASSETTE TEST (MFR # 5007, 5008)

PRODUCT NAME: CONSULT® H.PYLORI CASSETTE TEST

MFR #: 5007, 5008

1.1. Product identifier

Product form	:	Mixture
Product name	:	IHP-402 Negative Control
Product group	:	Blend

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	:	Professional use
Industrial/Professional use spec	:	For professional use only

1.2.2. Uses advised against

No additional information available

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9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908 Monday-Friday 8:00a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company)Day or Night

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP)	:	Warning
Hazard statements (CLP)	:	H302 - Harmful if swallowed H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP)	:	P264 - Wash hands thoroughly after handling P270 - Do not eat, drink or smoke when using this product P273 - Avoid release to the environment P330 - Rinse mouth P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
EUH phrases	:	EUH401 - To avoid risks to human health and the environment, comply with the instructions for use

2.3. Other hazards

Adverse physicochemical, human health and environmental effects	:	None under normal conditions. To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
Other hazards not contributing to the classification	:	None under normal conditions. This product contains material of human and animal origin.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tris (hydroxymethyl) aminomethane	(CAS No) 77-86-1 (EC no) 201-064-4	6.05	Xi; R36/37/38	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Sodium Azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	0.09	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Under normal conditions of use, no adverse effects to health have been observed.

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : None under normal use.

Symptoms/injuries after skin contact : None under normal use.

Symptoms/injuries after eye contact : None under normal use.

Symptoms/injuries after ingestion : None under normal use.

Symptoms/injuries upon intravenous administration : None under normal use.

Chronic symptoms : None under normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Foam.

Unsuitable extinguishing media : No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No direct or indirect fire hazard identified.

Explosion hazard : No direct explosion hazard.

Reactivity in case of fire : None under normal conditions.

Hazardous decomposition products in case of fire : fume.

5.3. Advice for firefighters

Precautionary measures fire : Evacuate area. Stop leak if safe to do so.

Firefighting instructions : No specific fire-fighting instructions required.

Protection during firefighting : Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No open flames. No smoking. Absorb spillage to prevent material damage.

6.1.1. For non-emergency personnel

Protective equipment : Protective clothing as deemed necessary.

Emergency procedures : Avoid contact with skin, eyes and clothing. Evacuate unnecessary personnel. Keep containers closed. No open flames, no sparks, and no smoking.

Measures in case of dust release : No effects known.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

Emergency procedures : Contain any material as necessary.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage and/or debris.

Methods for cleaning up : Carefully collect the spill/leftovers.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : No known hazards/None known.

Precautions for safe handling : Avoid contact during pregnancy/while nursing. Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Keep out of reach of children. No open flames. No smoking. Observe normal hygiene standards. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container closed when not in use. Keep container tightly closed. Keep only in original container. Store as directed in product literature . Store in original container.

Incompatible products : None known.

Incompatible materials : Away from heat sources.

Heat and ignition sources : No direct or indirect fire or ignition sources identified.

Prohibitions on mixed storage : None known.

Storage area : Keep container as directed in product literature.

Special rules on packaging : Keep only in original container. Proper handling and disposal methods should be established by the laboratory in accordance with local, state, federal and national regulations.

Packaging materials : No data available.

7.3. Specific end use(s)

None known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium Azide (26628-22-8)		
EU	IOELV TWA (mg/m³)	0.1 mg/m³
EU	IOELV STEL (mg/m³)	0.3 mg/m³
Belgium	Limit value (mg/m³)	0.1 mg/m³
Belgium	Short time value (mg/m³)	mg/m³
France	VME (mg/m³)	Azide de sodium,0.1 mg/m³; France; Time-weighted average exposure limit 8 h; VRC: Valeur réglementaire contraignante
France	VLE (mg/m³)	Azide de sodium,0.3 mg/m³; France; Short time value; VRC: Valeur réglementaire contraignante
Netherlands	Grenswaarde TGG 8H (mg/m³)	Natriumazide,0.1 mg/m³; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	Natriumazide,0.3 mg/m³; Netherlands; Short time value; Public occupational exposure limit value
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.29 mg/m³

Sodium Azide (26628-22-8)		
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls : Wear recommended personal protective equipment.

Personal protective equipment : Avoid all unnecessary exposure. Gloves. In case of splash hazard: safety glasses. Protective clothing.

Thermal hazard protection : Not applicable.

Environmental exposure controls : Avoid release to the environment.

Consumer exposure controls : Avoid contact during pregnancy/while nursing.

Other information : Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Tris (hydroxymethyl) aminomethane (77-86-1)	
LD50 oral rat	5900 mg/kg (Rat)

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

Potential adverse human health effects and symptoms : No data available.

Other information : Product is not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or Prop 65.

SECTION 12: Ecological information

12.1. Toxicity

Sodium Azide (26628-22-8)	
LC50 fish 1	0.8 mg/l 96 h; Salmo gairdneri (Oncorhynchus mykiss)
LC50 other aquatic organisms 1	1 (1 - 10) mg/l (96 h)
EC50 Daphnia 1	4.2 mg/l (48 h; Daphnia pulex)
EC50 other aquatic organisms 1	5 (5 - 14) mg/l (Protozoa; TOXICITY TEST)
LC50 fish 2	0.7 mg/l (96 h; Lepomis macrochirus)
TLM fish 1	1.5 ppm (24 h; Lepomis macrochirus)
Threshold limit other aquatic organisms 1	1 - 10,96 h

12.2. Persistence and degradability

Sodium Azide (26628-22-8)	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable
Tris (hydroxymethyl) aminomethane (77-86-1)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Sodium Azide (26628-22-8)	
Bioaccumulative potential	not bioaccumulable.
Tris (hydroxymethyl) aminomethane (77-86-1)	
Log Pow	-1.56
Bioaccumulative potential	Bioaccumulation: not applicable.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	:	Disposal must be done according to official regulations.
Waste treatment methods	:	Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	:	Disposal must be done according to official regulations.
Waste disposal recommendations	:	Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations. Used Alere Medical Test Device / Test Device Kits should be decontaminated and disposed of using an autoclave or by incineration as "other waste" - containing biological material. Biological waste material must be disposed of in accordance with your facility's biological safety program that is consistent with National, federal, state, and local regulations. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Unused Alere Controls should be disposed of in accordance with your facility's solid waste disposal policies.
Additional information	:	Clean up even minor leaks or spills if possible without unecessary risk.
Ecology - waste materials	:	Avoid release to the environment.
European List of Waste (LoW) code	:	18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	:	Not applicable
Proper Shipping Name (IMDG)	:	Not applicable
Proper Shipping Name (IATA)	:	Not applicable
Proper Shipping Name (ADN)	:	Not applicable
Proper Shipping Name (RID)	:	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR)	:	Not applicable
Packing group (IMDG)	:	Not applicable
Packing group (IATA)	:	Not applicable
Packing group (ADN)	:	Not applicable
Packing group (RID)	:	Not applicable

14.5. Environmental hazards

Dangerous for the environment	:	No
Marine pollutant	:	No
Other information	:	No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Not subject to ADN : No

- Rail transport

Carriage prohibited (RID) : No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 2, hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

Not listed under California Prop 65

SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H300	Fatal if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH401	To avoid risks to human health and the environment, comply with the instructions for use

R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R36/37/38	Irritating to eyes, respiratory system and skin
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
T+	Very toxic
Xi	Irritant

SDS EU (REACH Annex II)

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

2 of 2 SDS for CONSULT H.PYLORI CASSETTE TEST (MFR # 5007, 5008)

PRODUCT NAME: CONSULT® H.PYLORI CASSETTE TEST

MFR #: 5007, 5008

1.1. Product identifier

Product form	:	Mixture
Product name	:	IHP-402 Negative Control
Product group	:	Blend

1.2. Relevant identified uses of the substance or mixture and uses advised against

1... Relevant identified uses

Main use category	:	Professional use
Industrial/Professional use spec	:	For professional use only

2... Uses advised against

No additional information available

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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP)	:	Warning
Hazard statements (CLP)	:	H302 - Harmful if swallowed H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP)	:	P264 - Wash hands thoroughly after handling P270 - Do not eat, drink or smoke when using this product P273 - Avoid release to the environment P330 - Rinse mouth P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
EUH phrases	:	EUH401 - To avoid risks to human health and the environment, comply with the instructions for use

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium Azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	0.08995	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Under normal conditions of use, no adverse effects to health have been observed.

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : None under normal use.

Symptoms/injuries after skin contact : None under normal use.

Symptoms/injuries after eye contact : None under normal use.

Symptoms/injuries after ingestion : None under normal use.

Symptoms/injuries upon intravenous administration : None under normal use.

Chronic symptoms : None under normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Foam.

Unsuitable extinguishing media : No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No direct or indirect fire hazard identified.

Explosion hazard : No direct explosion hazard.

Reactivity in case of fire : None under normal conditions.

Hazardous decomposition products in case of fire : fume.

5.3. Advice for firefighters

Precautionary measures fire : Evacuate area. Stop leak if safe to do so.

Firefighting instructions : No specific fire-fighting instructions required.

Protection during firefighting : Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No open flames. No smoking. Absorb spillage to prevent material damage.

6.1.1. For non-emergency personnel

Protective equipment : Protective clothing as deemed necessary.

Emergency procedures : Avoid contact with skin, eyes and clothing. Evacuate unnecessary personnel. Keep containers closed. No open flames, no sparks, and no smoking.

Measures in case of dust release : No effects known.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

Emergency procedures : Contain any material as necessary.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage and/or debris.

Methods for cleaning up : Carefully collect the spill/leftovers.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : No known hazards/None known.

Precautions for safe handling : Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Keep out of reach of children. Observe normal hygiene standards. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations. Does not require any specific or particular technical measures.

Storage conditions : Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container closed when not in use. Keep only in original container. Store in original container. Store as directed in product literature.

Incompatible products : None known.

Incompatible materials : Away from heat sources.

Heat and ignition sources : No direct or indirect fire or ignition sources identified.

Prohibitions on mixed storage : None known.

Storage area : Keep container as directed in product literature.

Special rules on packaging : Keep only in original container. Proper handling and disposal methods should be established by the laboratory in accordance with local, state, federal and national regulations.

Packaging materials : No data available.

7.3. Specific end use(s)

None known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium Azide (26628-22-8)		
EU	IOELV TWA (mg/m³)	0.1 mg/m³
EU	IOELV STEL (mg/m³)	0.3 mg/m³
Belgium	Limit value (mg/m³)	0.1 mg/m³
Belgium	Short time value (mg/m³)	mg/m³
France	VME (mg/m³)	Azide de sodium,0.1 mg/m³; France; Time-weighted average exposure limit 8 h; VRC: Valeur réglementaire contraignante
France	VLE (mg/m³)	Azide de sodium,0.3 mg/m³; France; Short time value; VRC: Valeur réglementaire contraignante
Netherlands	Grenswaarde TGG 8H (mg/m³)	Natriumazide,0.1 mg/m³; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	Natriumazide,0.3 mg/m³; Netherlands; Short time value; Public occupational exposure limit value
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.29 mg/m³
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls : Wear recommended personal protective equipment.

Personal protective equipment : Avoid all unnecessary exposure. Gloves. In case of splash hazard: safety glasses. Protective clothing.

Thermal hazard protection	:	Not applicable.
Environmental exposure controls	:	Avoid release to the environment.
Consumer exposure controls	:	Avoid contact during pregnancy/while nursing.
Other information	:	Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	No data available
Odour	:	No data available
Odour threshold	:	No data available
pH	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	No data available
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified

Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	No data available.
Other information	:	Product is not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or Prop 65.

SECTION 12: Ecological information

12.1. Toxicity

Sodium Azide (26628-22-8)	
LC50 fish 1	0.8 mg/l 96 h; Salmo gairdneri (Oncorhynchus mykiss)
LC50 other aquatic organisms 1	1 (1 - 10) mg/l (96 h)
EC50 Daphnia 1	4.2 mg/l (48 h; Daphnia pulex)
EC50 other aquatic organisms 1	5 (5 - 14) mg/l (Protozoa; TOXICITY TEST)
LC50 fish 2	0.7 mg/l (96 h; Lepomis macrochirus)
TLM fish 1	1.5 ppm (24 h; Lepomis macrochirus)
Threshold limit other aquatic organisms 1	1 - 10,96 h

12.2. Persistence and degradability

Sodium Azide (26628-22-8)	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

12.3. Bioaccumulative potential

Sodium Azide (26628-22-8)	
Bioaccumulative potential	not bioaccumulable.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	:	Disposal must be done according to official regulations.
Waste treatment methods	:	Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	:	Disposal must be done according to official regulations.
Waste disposal recommendations	:	Avoid release to the environment. Used Innovacon Medical Test Device / Test Device Kits should be decontaminated and disposed of using an autoclave or by incineration as "other waste" - containing biological material. Biological waste material must be disposed of in accordance with your facility's biological safety program that is consistent with National, federal, state, and local regulations. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Unused Innovacon Controls should be disposed of in accordance with your facility's solid waste disposal policies.
Additional information	:	Clean up even minor leaks or spills if possible without unecessary risk.
Ecology - waste materials	:	Avoid release to the environment.

European List of Waste (LoW) code	:	18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	:	Not applicable
Proper Shipping Name (IMDG)	:	Not applicable
Proper Shipping Name (IATA)	:	Not applicable
Proper Shipping Name (ADN)	:	Not applicable
Proper Shipping Name (RID)	:	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	:	Not applicable

IMDG

Transport hazard class(es) (IMDG)	:	Not applicable

IATA

Transport hazard class(es) (IATA)	:	Not applicable

ADN

Transport hazard class(es) (ADN)	:	Not applicable

RID

Transport hazard class(es) (RID)	:	Not applicable

14.4. Packing group

Packing group (ADR)	:	Not applicable
Packing group (IMDG)	:	Not applicable
Packing group (IATA)	:	Not applicable
Packing group (ADN)	:	Not applicable
Packing group (RID)	:	Not applicable

14.5. Environmental hazards

Dangerous for the environment	:	No
Marine pollutant	:	No
Other information	:	No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Not subject to ADN	:	No

- Rail transport

Carriage prohibited (RID)	:	No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference	:	Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)
12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV	:	Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	SERUM ALBUMIN is listed
SZW-lijst van mutagene stoffen	:	SERUM ALBUMIN is listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	None of the components are listed

15.2. Chemical safety assessment

Not listed under California Prop 65

SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH401	To avoid risks to human health and the environment, comply with the instructions for use
R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
T+	Very toxic

SDS EU (REACH Annex II)

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

MCKESSON SAFETY DATA SHEET SDS DATE: 11.19.15

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME: CONSULT® hCG Dipstick (5000), CONSULT® hCG Urine Cassette Test (5001), CONSULT® hCG Combo cassette test (5002),

MFR #: 5000 (Dipstick); 5001 (Cassette); 5002 (Combo Cassette)

DISTRIBUTEDBY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908 Monday-Friday 8:00a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company) Day or Night

PRODUCT DESCRIPTION/IDENTIFIED USES: *In vitro* diagnostic reagent. For professional use only.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)	Eye Irrit. 2
Hazard statement(s)	H319: Causes serious eye irritation.
Directive 67/548/EEC & Directive 1999/45/EC	Not classified as dangerous for supply/use.
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) /GHS	Eye Irrit. 2
Hazard statement(s)	Causes serious eye irritation.

2.2 Label elements — No measures required. The product is placed on the market in the form of an article, which contains insignificant quantities of hazardous chemicals that are not intended to be released from the device.

2.3 Other hazards — None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Description: In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:
EC Classification No. 1272/2008 / GHS

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	Classification code: Hazard statement(s)
Sodium carbonate	1 - 2	207-838-8	497-19-8	Eye Irrit. 2; H319
Triton X100*	1 - 2	-	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411
Sodium azide**	< 0.1	247-852-1	26628-22-8	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	EC Classification and Risk Phrases

Sodium carbonate	1 - 2	207-838-8	497-19-8	Xi; R36
Triton X100*	1 - 2	-	9002-93-1	Xn; R22-41-51/53
Sodium azide**	< 0.1	247-852-1	26628-22-8	T+, N; R28-32-50/53

* candidate substance of very high concern (SVHC)

** Substance with a community exposure limit

3.3 Additional Information — For full text of R/H phrases see section 16. Each device is packaged in a foil pouch.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information: The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

Inhalation: Supply fresh air; consult doctor in case of complaint.

Skin Contact: Wash skin with soap and water.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Ingestion: Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed — None.

4.3 Indication of the immediate medical attention and special treatment needed — None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture — In case of fire, the following can be released: Hazardous fumes, Carbon oxides (COx), nitrogen oxides (NOx).

5.3 Advice for fire-fighters — Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures — Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions — Avoid release to the environment.

6.3 Methods and material for containment and cleaning up — Collect material and dispose of as waste according to Section 13.

6.4 Reference to other sections — 8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling — Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.

Clean work areas with hypochlorite or other disinfecting agent.

7.2 Conditions for safe storage, including any incompatibilities — Store in the original container at 2 to 30°C.

7.3 Specific end use(s) — Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits — EU IOELV / UK WEL / Irl OELV

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note:
Sodium Azide	26628-22-8		0.1		0.3	Sk

Sk - Can be absorbed through skin.

8.2 Exposure controls

8.2.1 Appropriate engineering controls — Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection — Safety glasses recommended. (EN166)

Hand protection — Disposable gloves. (EN374).

Material of gloves: — Latex / natural rubber, Nitrile rubber.

Penetration time of glove material: — Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection — Laboratory coat.

Respiratory protection — Not normally required.

8.2.3 Environmental Exposure Controls — No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Laminated test strip, which may be housed in a plastic holder.
Colour	Variable depending on product.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not determined.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (mm Hg)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not applicable.
Solubility (Water)	Not determined.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising

9.2 Other information — Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1	**Reactivity**	None known.
10.2	**Chemical stability**	The product is stable in accordance with therecommended storage conditions.
10.3	**Possibility of hazardous reactions**	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4	**Conditions to avoid**	None.
10.5	**Incompatible materials**	None.
10.6	**Hazardous Decomposition Product(s)**	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Causes serious eye irritation.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are not met.
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2	**Persistence and degradability**	The device contains plastic and other components that are not readily degradable.
12.3	**Bioaccumulative potential**	None anticipated.
12.4	**Mobility in soil**	The product is predicted to have low mobility in soil.
12.5	**Results of PBT and vPvB assessment**	Not applicable.
12.6	**Other adverse effects**	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.
Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/oran

	approved waste-disposal company for information.
European waste catalogue:	18 01 03.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	**UN number**	Not applicable
14.2	**UN Proper Shipping Name**	Not applicable
14.3	**Transport hazard class(es)**	Not classified as dangerous for transport.
14.4	**Packing Group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special precautions for user**	Not applicable
14.7	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	**Safety, health and environmental regulations/legislation specific for the substance or mixture**	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA:	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	Sodium azide (trace).
	Section 313 (specific toxic chemical listings):	Sodium azide (trace).
15.2	**Chemical Safety Assessment**	Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT	Specific Target Organ Toxicity
STEL	Short Term Exposure Limit
LTEL	Long Term Exposure limit
TWA	Time Weighted Average

Classification code:

Acute Tox. 4	Acute toxicity; Category 4
Acute Tox. 2	Acute toxicity: Category 2
Eye Dam. 1	Eye damage; Category 1
Eye Irrit. 2	Eye Irritation: Category 2
Aquatic Acute 1	Hazardous to the aquatic environment Acute: Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment Chronic: Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment Chronic: Category 2

Xi	rritant
Xn	Harmful.
T+	Very toxic.
N	Dangerous for theenvironment.

Hazard statement(s)

H300: Fatal if swallowed.
H302: Harmful ifswallowed.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lastingeffects.
H411: Toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxicgas.

Risk Phrases

R22: Harmful if swallowed.
R28: Very toxic ifswallowed.
R32: Contact with acids liberates very toxic gas.
R36: Irritating to eyes.
R41: Risk of serious damage toeyes.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

References:

Raw material safety data sheets.

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MSDS DATE: 01/13/2015

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: CONSULT® Strep A Test
REORDER #: 4999 (50T/Kit); 5003 (25T/Kit)

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
8741 Landmark Road
Richmond, VA 23228

INFORMATION LINE: 1-800-777-4908

EMERGENCY PHONE: 1-800-424-9300 (CHEMTREC)

PRODUCT DESCRIPTION: In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents. For professional use only.

SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	EINECS NO.	CLASSIFICATION	CONCENTRATION %
Tris (hydroxymethyl) aminomethane	77-86-2	201-064-4	Xi, R 36/37/38	10—20%
Sodium Carbonate	497-19-8	207-838-8	Xi, R 36	5—10%

SECTION 2 NOTES: As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200. Each device is packaged in a foil pouch.

SECTION 3: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Eye contact, skin contact

POTENTIAL HEALTH EFFECTS

EYES: Irritating effect following contact with the chemicals impregnated in the test strip. **SKIN:** Contact with the chemicals impregnated in the test strip may cause mild irritation **INGESTION:** N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY

OSHA: N/A **ACGIH:** N/A **NTP:** N/A **IARC:** N/A
OTHER: N/A

SECTION 3 NOTES: N/A

SECTION 4: FIRST-AID MEASURES

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

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EYES: Immediately rinse opened eye for several minutes under running water. Seek medical advice.

SKIN: Wash with soap and water and rinse thoroughly. Consult a doctor if irritation persists.

INGESTION: If desiccant or other components are swallowed, seek medical attention.

INHALATION: N/A

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: N/A
(% BY VOLUME) LOWER: N/A

FLASH POINT: N/A
METHOD USED: N/A

AUTOIGNITION TEMPERATURE: Not self-igniting

NFPA HAZARD CLASSIFICATION
HEALTH: N/A **FLAMMABILITY:** N/A **REACTIVITY:** N/A
OTHER: N/A

HMIS HAZARD CLASSIFICATION
HEALTH: N/A **FLAMMABILITY:** N/A **REACTIVITY:** N/A
PROTECTION: N/A

EXTINGUISHING MEDIA: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding conditions.

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

UNUSUAL FIRE AND EXPLOSION HAZARDS: The device contains combustible materials. Product does not present an explosion hazard.

HAZARDOUS DECOMPOSITION PRODUCTS: In case of fire, the following may be released: hazardous fumes and vapors, carbon oxides and nitrogen oxides.

SECTION 5 NOTES:

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Collect material and dispose of as waster according to Section 13. Avoid release to the environment.

SECTION 6 NOTES: Refer to Section 8 for protective measures when handling the spillage.

SECTION 7: HANDLING AND STORAGE

HANDLING: N/A

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STORAGE: Store in the original container at 2—30°C

OTHER PRECAUTIONS: Keep out of reach of children

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING

CONTROLS:

VENTILATION: N/A

RESPIRATORY PROTECTION: Not required

EYE PROTECTION: Not required

SKIN PROTECTION: Latex/natural rubber disposable gloves (for sample handling); Lab coat

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: Specimens should be handled as potentially infectious materials. Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

EXPOSURE GUIDELINES: The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Laminated test strip; odorless

PHYSICAL STATE: The device is an article containing solid components

pH AS SUPPLIED: N/A
pH (Other: N/A
BOILING POINT:
N/A **MELTING**
POINT: N/A
FREEZING POINT:
N/A
VAPOR PRESSURE (mmHg): N/A
@ N/A
VAPOR DENSITY (AIR = 1): N/A
@ N/A
SPECIFIC GRAVITY (H2O = 1): N/A
@ N/A
EVAPORATION RATE:

N/A **BASIS (=1):** N/A

SOLUBILITY IN WATER:

N/A

PERCENT SOLIDS BY WEIGHT: N/A

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PERCENT VOLATILE: N/A
BY WT/ N/A **BY VOL @** N/A

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

WITH WATER: N/A **LBS/GAL**
WITHOUT WATER: N/A **LBS/GAL**

MOLECULAR WEIGHT: N/A
VISCOSITY: N/A
@
N/
A

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

	STABLE	UNSTABLE
STABILITY:	**X**	

CONDITIONS TO AVOID (STABILITY): None

INCOMPATIBILITY (MATERIAL TO AVOID): None

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: No dangerous decomposition product known

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION):

N/A **SECTION 10 NOTES:** N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: Quantitative data on the toxic effects of this product is not available; No sensitizing effects known

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: Quantitative data on the toxic effects of this product is not available. The device contains plastic and other components that are not readily degradable.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Used devices and other contaminated materials should be disposed of as potentially bio-hazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact relevant (local) authorities and/or an approved waste-disposal company for information. Disposal must be made in accordance with local waste

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MSDS DATE: 01/13/2015

management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION PROPER SHIPPING NAME: N/A **HAZARD CLASS:** N/A
DOT SHIPPING ID NUMBER: N/A **DOT PACKING GROUP:** N/A **DOT LABEL STATEMENT:** N/A

WATER TRANSPORTATION
PROPER SHIPPING NAME: N/A **HAZARD CLASS:** N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

AIR TRANSPORTATION
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A **ID NUMBER:** N/A **PACKING GROUP:** N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: Not regulated for transport

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS
TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A
311/312 HAZARD CATEGORIES: N/A

313 REPORTABLE INGREDIENTS:

N/A **STATE REGULATIONS:** N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: Labeling according to EU guidelines: Code letter and hazard designation of product: Xi (Irritant)

RISK PHRASES: 36 Irritating to Eyes

SAFETY PHRASES: S2 Keep out of reach of children; 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice; 46 If swallowed, seek medical advice immediately and show this container or label; 60 This material and its container must be disposed of as hazardous waste.

PREPARATION INFORMATION: The preparation is exempt from the above labeling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 81911-75 Rev. AJ
Revised (year/month/day) 2015/04/14

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name CONTRAD® 70

Part Number 81911

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Distributed by Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Eurocenter S.A. 22, rue Juste-Oliver, Case Postale 1044, CH-1260 Nyon 1, Switzerland. Telephone +41 (0)22 365 36 11 Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

White; Translucent; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

C;R34

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Potassium Hydroxide

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Potassium Hydroxide CAS # 1310-58-3 EINECS # 215-181-3 Index # 019-002-00-8	1 - 5	C;R22-35	Acute Tox. Oral 4 Eye Dam. 1 Skin Corr. 1A H302; H314; H318	Acute Tox. Oral 4 Aquatic Acute 3 Eye Dam. 1 Skin Corr. 1A H302; H314; H318; H402	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open and obtain medical attention immediately.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Corrosive. May cause burns to eyes, skin and respiratory tract.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

If eye irritation persists: Get medical advice/attention.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Observe general safety guidelines for protection; avoid eye and skin contact.
Avoid inhaling, ingesting, and contact with eyes and skin.

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Section 6 Accidental Release Measures (Continued)

6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	Use good laboratory procedures; avoid eye and skin contact.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 15 to 30°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**Specific end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	
	Potassium Hydroxide CAS # 1310-58-3	2 mg/m3 Ceiling
	DFG MAK	None established
	Ireland	
	Potassium Hydroxide CAS # 1310-58-3	2 mg/m3 STEL
	IOELVs	None established
	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.06 @20°C
Color	White	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	13	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	> 212°C (413.6°F)	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Potassium Hydroxide CAS # 1310-58-3	Oral LD50 Rat 214 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Causes severe skin burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability

Not determined for the product.

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Section 12 Ecological Information (Continued)

12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	**UN/ID Number**	1814	1814	1814	1814	PIN - 1814
14.2	**Shipping Name**	Potassium Hydroxide Solution				
14.3	**Hazard Class**	8 Corrosives	8 Corrosive substances	ORM-D Consumer Commodity	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	**Packing Group**	II	II	II	II	II
	Special Provisions	Not applicable	None	DOT Exception 153.154(c) (US ground only)	Not applicable	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154

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Section 14 Transport Information (Continued)

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 Potassium Hydroxide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Potassium Hydroxide is listed.

New Jersey Dept. of Health RTK List

Potassium Hydroxide is listed.

Pennsylvania RTK Potassium Hydroxide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Corrosive
C

Risk and Safety Phrases

R34 Causes burns.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1814

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Potassium Hydroxide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
R22 Harmful if swallowed.
R35 Causes severe burns.
Aquatic Acute 3 - Aquatic Hazard Acute, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.
H402 - Harmful to aquatic life.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program

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Section 16 Other Information (Continued)

OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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Kit SDS Cover Sheet

Doc. ID: 33600-75: Rev. AG
Revised (year/month/day) 2015/04/21

Product Information

Product Name	CORTISOL
Part Number	33600
Series Name	ACCESS®

Components

Description	Cortisol Particles/Conjugate (Compartment R1a) Cortisol Antibody (Compartment R1b)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 33600-75 Rev. AG
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Cortisol Particles/Conjugate (Compartment R1a)

Part Number Component of P/N 33600

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address
Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	≈ 8	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Global SDS – English

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.

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Section 16 Other Information (Continued)

	R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33600-75 Rev. AG
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Cortisol Antibody (Compartment R1b)

Part Number Component of P/N 33600

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	≈ 8	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Global SDS – English

Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 628022-75 Rev. AE
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name COULTER DxH Cleaner

Part Number 628022, 628023

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Blue; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Respiratory Sensitization Category 1
Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Respiratory Sensitization Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Subtilisin

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

DANGER

Hazard Statements

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P284 In case of inadequate ventilation, wear respiratory protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

Subtilisin CAS # 9014-01-1 EINECS # 232-752-2 Index # 647-012-00-8	0.1 - 0.5	Xn;R37/38-41-42	Eye Dam. 1 Resp. Sens. 1 STOT SE 3 Skin Irrit. 2 H315; H318; H334; H335	Acute Tox. Oral 5 Eye Dam. 1 Resp. Sens. 1 STOT SE 3 Skin Irrit. 2 H303; H315; H318; H334; H335	
Ethoxylated Nonylphenol CAS # 68412-54-4 EINECS # Not available Index # Not available	< 0.5	Xi;R38-41 N;R51/53	Acute Tox. Oral 4 Aquatic Longterm 2 Eye Dam. 1 Skin Irrit. 2 H302; H315; H318; H411	Acute Tox. Oral 4 Aquatic Longterm 2 Eye Dam. 1 Skin Irrit. 2 H302; H315; H318; H411	8, SVHC
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	10

10 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 150.
8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Subtilisin CAS # 9014-01-1	0.00006 mg/m3 Ceiling (as as crystalline active enzyme) (listed under Subtilisins)
DFG MAK	None established
Ireland	
Subtilisin CAS # 9014-01-1	0.00006 mg/m3 TWA (Proteolytic enzymes) (as 100% pure crystalline enzyme); 0.00006 mg/m3 STEL
IOELVs	None established
NIOSH	
Subtilisin CAS # 9014-01-1	0.00006 mg/m3 STEL (60 min) (listed under Subtilisins)
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Blue	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.5 - 8.9	**Partition coefficient: n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Subtilisin CAS # 9014-01-1	Oral LD50 Rat 3700 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.

1,4-Dioxane is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.

Ethylene Glycol Monobutyl Ether is listed.

1,4-Dioxane is listed.

Magnesium Nitrate is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.

Ethylene Glycol Monobutyl Ether is listed.

1,4-Dioxane is listed.

Patent Blue VF is listed.

Lithium Hydroxide Monohydrate is listed.

Magnesium Nitrate is listed.

Pennsylvania RTK

Ethylene Oxide is listed.

Ethylene Glycol Monobutyl Ether is listed.

1,4-Dioxane is listed.

Magnesium Nitrate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Ethylene Oxide
Ethylene Glycol Monobutyl Ether
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
Xi - Irritant
Xn - Harmful
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R37/38 Irritating to respiratory system and skin.
R41 Risk of serious damage to eyes.
R42 May cause sensitization by inhalation.
R38 Irritating to skin.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

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Section 16 Other Information (Continued)

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
Resp. Sens. 1 - Respiratory Sensitization Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H303 - May be harmful if swallowed
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act

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Section 16 Other Information (Continued)

TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 628018-75 Rev. AF
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Coulter® DxH Cell Lyse

Part Number 628018, 628019

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R36

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Tetradecyltrimethylammonium bromide

Dodecyltrimethylammonium chloride

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

H402 Harmful to aquatic life.

Precautionary Statements

P273 Avoid release to the environment.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.1.4% of product contains ingredients of unknown hazards to the aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Dodecyltrimethylammonium chloride CAS # 112-00-5 EINECS # 203-927-0 Index # Not available	1 - 5	Xn;R20/21/22	Aquatic Acute 1 Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335; H400	Aquatic Acute 1 Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335; H400	
Isopropyl Alcohol CAS # 67-63-0 EINECS # 200-661-7 Index # 603-117-00-0	< 3	F;R11 Xi;R36-67	Eye Irrit. 2 Flam. Liq. 2 STOT SE 3 H225; H319; H336	Eye Irrit. 2 Flam. Liq. 2 STOT SE 3 H225; H319; H336	3, 8
Tetradecyltrimethylammonium bromide CAS # 1119-97-7 EINECS # 214-291-9 Index # Not available	< 3	C;R34	Aquatic Acute 1 Eye Dam. 1 Skin Corr. 1C H314; H318; H400	Aquatic Acute 1 Eye Dam. 1 Skin Corr. 1C H314; H318; H400	

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Section 3 Composition and Information on Ingredients (Continued)

3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 40°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Isopropyl Alcohol
CAS # 67-63-0 400 ppm TWA; 980 mg/m3 TWA

ACGIH

Isopropyl Alcohol
CAS # 67-63-0 400 ppm STEL; 200 ppm TWA

DFG MAK

Isopropyl Alcohol
CAS # 67-63-0 400 ppm Peak; 1000 mg/m3 Peak; 200 ppm TWA MAK; 500 mg/m3 TWA MAK

Ireland

Isopropyl Alcohol
CAS # 67-63-0 200 ppm TWA; 400 ppm STEL; Potential for cutaneous absorption

IOELVs None established

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Section 8 Exposure Controls and Personal Protection (Continued)

NIOSH	
Isopropyl Alcohol CAS # 67-63-0	2000 ppm IDLH (10% LEL); 500 ppm STEL; 1225 mg/m3 STEL; 400 ppm TWA; 980 mg/m3 TWA
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	0.996 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	9.80 - 10.20	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Isopropyl Alcohol 43 ppm geometric mean air odor threshold = (detectable); 19 ppm geometric mean air odor threshold = (recognizable)
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	No further relevant information available.
10.4	**Conditions to Avoid**	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Isopropyl Alcohol CAS # 67-63-0	Inhalation LC50 Rat 72.6 mg/L 4 h; Oral LD50 Rat 4396 mg/kg; Dermal LD50 Rat 12800 mg/kg; Dermal LD50 Rabbit 12870 mg/kg
Tetradecyltrimethylammonium bromide CAS # 1119-97-7	Oral LD50 Rat 3900 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Isopropyl Alcohol
CAS # 67-63-0 — 96 h LC50 Pimephales promelas: 9640 mg/L [flow-through]; 96 h LC50 Pimephales promelas: 11130 mg/L [static]; 96 h LC50 Lepomis macrochirus: >1400000 µg/L

Microtox — No information available.

Water Flea

Isopropyl Alcohol
CAS # 67-63-0 — 48 h EC50 Daphnia magna: 13299 mg/L

Fresh Water Algae

Isopropyl Alcohol
CAS # 67-63-0 — 96 h EC50 Desmodesmus subspicatus: >1000 mg/L; 72 h EC50 Desmodesmus subspicatus: >1000 mg/L

12.2 Persistence and degradability — Not determined for the product.

12.3 Bioaccumulation — Not determined for the product.

12.4 Mobility in soil — Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects — Harmful to aquatic life.

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal — Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information — Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Isopropyl Alcohol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration (only

CERCLA RG's, 40 CFR 302.4 Sodium Hydroxide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL
Isopropyl Alcohol is listed.
Sodium Hydroxide is listed.
Trisodium Nitrilotriacetate is listed.

New Jersey Dept. of Health RTK List
Isopropyl Alcohol is listed.
Sodium Hydroxide is listed.

Pennsylvania RTK
Isopropyl Alcohol is listed.
Sodium Hydroxide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 2, water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases
R36 Irritating to eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List
Isopropyl Alcohol
Sodium Hydroxide

Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
F - Highly flammable
Xi - Irritant
Xn - Harmful
R11 Highly flammable.
R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R36 Irritating to eyes.
R67 Vapours may cause drowsiness and dizziness.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Flam. Liq. 2 - Flammable Liquids, Category 2
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H225 - Highly flammable liquid and vapour.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H336 - May cause drowsiness or dizziness.
H400 - Very toxic to aquatic life.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization

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Section 16 Other Information (Continued)

IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: 628020-75: Rev. AF
Revised (year/month/day) 2015/03/31

Product Information

Product Name Coulter® DxH Diff Pack

Part Number 628020

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

StabiLyse™ Reagent
Erythrolyse II Reagent

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 628020-75 Rev. AF
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name StabiLyse™ Reagent

Part Number Component of P/N 628020

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.05 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	11	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Sulfate is listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK Sodium Sulfate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Carbonate

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated to GHS.	
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - Internal Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations.	

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Section 16 Other Information (Continued)

UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 628020-75 Rev. AF
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Erythrolyse II Reagent

Part Number Component of P/N 628020

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Light yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Formic Acid

Diazolidinyl Urea

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

EUH208 May produce an allergic reaction.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Formic Acid CAS # 64-18-6 EINECS # 200-579-1 Index # 607-001-00-0	< 1	C;R35	Acute Tox. Oral 4 Eye Dam. 1 Skin Corr. 1A H302; H314; H318	Acute Tox. Oral 4 Aquatic Acute 3 Eye Dam. 1 Flam. Liq. 4 Skin Corr. 1A H227; H302; H314; H318; H402	
Diazolidinyl Urea CAS # 78491-02-8 EINECS # 278-928-2 Index # Not available	< 0.1	Xi;R43	Skin Sens. 1 H317	Acute Tox. Dermal 5 Acute Tox. Oral 5 Skin Sens. 1 H303; H313; H317	15, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.0015	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	10, 15, 8

10 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 150.
15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Formic Acid CAS # 64-18-6	5 ppm TWA; 9 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Formic Acid CAS # 64-18-6	10 ppm STEL; 5 ppm TWA

DFG MAK

Formic Acid CAS # 64-18-6	10 ppm Peak; 19 mg/m3 Peak; 5 ppm TWA MAK; 9.5 mg/m3 TWA MAK

Ireland

Formic Acid CAS # 64-18-6	5 ppm TWA; 9 mg/m3 TWA

IOELVs

Formic Acid CAS # 64-18-6	5 ppm TWA; 9 mg/m3 TWA

NIOSH

Formic Acid CAS # 64-18-6	30 ppm IDLH; 5 ppm TWA; 9 mg/m3 TWA

Japan

Formic Acid CAS # 64-18-6	5 ppm OEL; 9.4 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0 @20°C
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

pH	2.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formic Acid no geometric mean air odor threshold		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Formic Acid CAS # 64-18-6	Oral LD50 Rat 730 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Causes mild skin irritation.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	
	Formic Acid CAS # 64-18-6	48 h EC50 Daphnia magna: 120 mg/L; 48 h EC50 Daphnia magna: 138 - 165.6 mg/L [Static]
	Fresh Water Algae	
	Formic Acid CAS # 64-18-6	96 h EC50 Desmodesmus subspicatus: 25 mg/L; 72 h EC50 Desmodesmus subspicatus: 26.9 mg/L
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Formic Acid is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Formic Acid is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Formic Acid is listed.
Magnesium Nitrate is listed.

New Jersey Dept. of Health RTK List

Formic Acid is listed.
Magnesium Nitrate is listed.

Pennsylvania RTK

Formic Acid is listed.
Magnesium Nitrate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Formic Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
N - Dangerous for the environment
T - Toxic
Xi - Irritant
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R35 Causes severe burns.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Aquatic Acute 3 - Aquatic Hazard Acute, Category 3
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Eye Dam. 1 - Eye Damage Category 1

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Section 16 Other Information (Continued)

Flam. Liq. 4 - Flammable Liquids, Category 4
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H227 - Combustible Liquid
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H303 - May be harmful if swallowed
H311 - Toxic in contact with skin.
H313 - May be harmful In contact with skin
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H402 - Harmful to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: 467830-75: Rev. AK
Revised (year/month/day) 2016/10/21

Product Information

Product Name	Creatine Kinase Reagent (N-Acetyl-L-cysteine)
Part Number	467830
Series Name	SYNCHRON Systems

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

CK Buffer (Compartment A)
CK Coenzyme (Compartment B)
CK Substrate (Compartment C)

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 467830-75 Rev. AK
Revised (year/month/day) 2016/10/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name CK Buffer (Compartment A)

Part Number Component of P/N 467830

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Sulfurous

Classification according to EC 1272/2008 (CLP/GHS)

Toxic to Reproductive Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Imidazole

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.
H316 Causes mild skin irritation.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P332+P313 If skin irritation occurs: Get medical advice/attention.
P405 Store locked up.
P308+P313 IF exposed or concerned: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Imidazole CAS # 288-32-4 EINECS # 206-019-2 Index # Not available	<1	Xn;R22 C;R34	Acute Tox. Oral 4 Repr. 1B Skin Corr. 1C H302; H314; H360	Acute Tox. Oral 4 Repr. 1B Skin Corr. 1C H302; H314; H360	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

May damage fertility or the unborn child.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	Use good laboratory procedures; avoid eye and skin contact.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 2 to 8°C , as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**Specific end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	None established
	DFG MAK	None established
	Ireland	None established
	IOELVs	None established
	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈1.007 @22-26°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Sulfurous	**Organic**	Not determined
pH	6.65 - 6.75 @23.5-24.5°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Global SDS – English

Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Imidazole CAS # 288-32-4	Oral LD50 Rat 220 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Causes mild skin irritation.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

Not classified based on available data.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not classified based on available data.

Reproductive Toxicity

May damage fertility or the unborn child.

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

No information available.

Microtox

No information available.

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Section 12 Ecological Information (Continued)

Water Flea

Imidazole CAS # 288-32-4	48 h EC50 Daphnia magna: 341.5 mg/L

Fresh Water Algae

Imidazole CAS # 288-32-4	72 h EC50 Desmodesmus subspicatus: 130 mg/L; 96 h EC50 Desmodesmus subspicatus: 82 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Update of product hazard classifications and label elements in Sec. 2. Revised Beckman Coulter safety rating.	

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Section 16 Other Information (Continued)

	Updated section 4,8,11,13
Hazard Class, hazard statements and risk phrase description from section 3	
	C - Corrosive
	Xn - Harmful
	R22 Harmful if swallowed.
	R34 Causes burns.
	Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
	Skin Corr. 1C - Skin Corrosion Category 1C
	Repr. 1B - Toxic to Reproductive Category 1B
	H302 - Harmful if swallowed.
	H314 - Causes severe skin burns and eye damage.
	H360 - May damage fertility or the unborn child.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA DGR - International Air Transport Association Dangerous Goods Regulation
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LD50 - Lethal Dose, 50%
	EC50 - Effective Concentration, 50%

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SAFETY DATA SHEET

Doc. ID: 467830-75 Rev. AK
Revised (year/month/day) 2016/10/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name CK Coenzyme (Compartment B)

Part Number Component of P/N 467830

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless to slightly yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Imidazole
Tris(hydroxymethyl)– aminomethane
Triphosphopyridine Nucleotide, Sodium Salt Hydrate

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.
H316 Causes mild skin irritation.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P332+P313 If skin irritation occurs: Get medical advice/attention.
P405 Store locked up.
P308+P313 IF exposed or concerned: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Triphosphopyridine Nucleotide, Sodium Salt Hydrate CAS # 1184-16-3 EINECS # 214-664-6 Index # Not available	1 - 5	No	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	

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Section 3 Composition and Information on Ingredients (Continued)

Tris(hydroxymethyl)–aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Xi;R36/37/38	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	
Imidazole CAS # 288-32-4 EINECS # 206-019-2 Index # Not available	< 1	Xn;R22 C;R34	Acute Tox. Oral 4 Repr. 1B Skin Corr. 1C H302; H314; H360	Acute Tox. Oral 4 Repr. 1B Skin Corr. 1C H302; H314; H360	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

May damage fertility or the unborn child.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈1.159 @22-26°C
Color	Colorless to slightly yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.4 - 6.6 @20-28°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Imidazole CAS # 288-32-4	Oral LD50 Rat 220 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	May damage fertility or the unborn child.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

Microtox No information available.

Water Flea

Imidazole
CAS # 288-32-4 — 48 h EC50 Daphnia magna: 341.5 mg/L

Fresh Water Algae

Imidazole
CAS # 288-32-4 — 72 h EC50 Desmodesmus subspicatus: 130 mg/L; 96 h EC50 Desmodesmus subspicatus: 82 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Glycerol is listed.

New Jersey Dept. of Health RTK List

Glycerol is listed.

Pennsylvania RTK Glycerol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

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Section 15 Regulatory Information (Continued)

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Update of product hazard classifications and label elements in Sec. 2.
Revised Beckman Coulter safety rating.
Updated section 4,8,11,13

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
Xi - Irritant
Xn - Harmful
R22 Harmful if swallowed.
R34 Causes burns.
R36/37/38 Irritating to eyes, respiratory system and skin.
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Irrit. 2 - Eye Irritation Category 2
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
Repr. 1B - Toxic to Reproductive Category 1B
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H360 - May damage fertility or the unborn child.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 467830-75 Rev. AK
Revised (year/month/day) 2016/10/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name CK Substrate (Compartment C)

Part Number Component of P/N 467830

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless to slightly yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

	IOELVs	None established
	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈1.147 @22-26°C
Color	Colorless to slightly yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.4 - 8.6 @20-28°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity
No further relevant information available.

10.2 Chemical Stability
The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions
No further relevant information available.

10.4 Conditions to Avoid
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials
No further relevant information available.

10.6 Hazardous Decomposition Products
No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients
Not applicable

Primary Routes of Exposure
Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation
Not classified based on available data.

Serious eye damage/eye irritation
Not classified based on available data.

Respiratory/skin sensitization
Not classified based on available data.

Carcinogenicity
No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity
Not classified based on available data.

Reproductive Toxicity
Not classified based on available data.

Specific target organ toxicity – single exposure
Not classified based on available data.

Specific target organ toxicity – repeated exposure
Not classified based on available data.

Aspiration hazard
Not classified based on available data.

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Section 11 Toxicological Information (Continued)

Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

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14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Glycerol is listed.

New Jersey Dept. of Health RTK List

Glycerol is listed.

Pennsylvania RTK Glycerol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated Section 4, 8, 11.	
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances	

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Kit SDS Cover Sheet

Document ID: OSR6199-75: Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/04/02

Product Information

Product Name	CRP LATEX
Part Number	OSR6199, OSR6299

Components

Description	CRP latex R1 CRP latex R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

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SAFETY DATA SHEET

Document ID: OSR6199-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/04/02

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name CRP latex R1

Part Number Component of P/N OSR6199, OSR6299

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Slighty turbid; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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BECKMAN COULTER
CRP LATEX
CRP latex R1

SAFETY DATA SHEET
Document ID: OSR6199-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/04/02

Section 2 Hazards (Continued)

2.2 Label Elements — **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Yellowish	**Solubility**	
Transparency	Slighty turbid	**Water**	Fully miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	7	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated section 4, 8, 11, 12, 14, 15, 16.

Document version and issue/revision date

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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name CRP latex R2

Part Number Component of P/N OSR6199, OSR6299

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

White; Opaque; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	White	**Solubility**	
Transparency	Opaque	**Water**	Fully miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	7.3	**Partition n-octanol/water**	Not determined
Freezing Point	0°C (32°F)	**Auto-ignition Temp.**	Product is not
Boiling Point	100°C (212°F)	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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BECKMAN COULTER
CRP LATEX
CRP latex R2

SAFETY DATA SHEET
Document ID: OSR6199-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/04/02

Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated section 4, 8, 11, 12, 14, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/04/02
Document ID: OSR6199-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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BECKMAN COULTER
CRP LATEX
CRP latex R2

SAFETY DATA SHEET

Document ID: OSR6199-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/04/02

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER
CRP Latex Calibrator Highly Sensitive (HS) Set

SAFETY DATA SHEET

Document ID: ODC0027-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name CRP Latex Calibrator Highly Sensitive (HS) Set

Part Number ODC0027

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light brown; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Light brown	**Solubility**	
Transparency	Clear	**Water**	Not miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	Not determined	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated section 4, 6, 8, 10, 11, 14, 16.

Updated Section 12.

Updated Section 15 Regulatory Information.

Document version and issue/revision date

Revision Date (year/month/day) 2019/07/03

Last Revision Date (year/month/day) 2015/03/20

Document ID: ODC0027-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

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Section 16 Other Information (Continued)

WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

1 Identification

· **Product identifier**

· **Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack**

· **Catalog or product number:** 290-1004
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable
· **Classification system**
· **Special Hazards** Contains human sourced and/or potentially infectious components.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

	Human Whole Blood	35-50%
6138-23-4	d-trehalose dihydrate	20-35%
56-40-6	glycine	20-35%

· **Additional information**
Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack

(Contd. of page 1)

· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack

(Contd. of page 2)

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
56-40-6 glycine	
REL (United States)	Long-term value: 1 mg/m³ as Fe
TLV (United States)	Long-term value: 1 mg/m³ as Fe

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** Follow the usual biosafety practices for handling infectious materials.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Color:	Red
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous)**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.

(Contd. on page 4)

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Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack

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Upper:	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Soluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Solids content:	100.0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

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Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack

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· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number**
· **DOT, ADR, ADN, IMDG, IATA** Not Regulated

· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** Not Regulated

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**
· **Class** Not Regulated

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Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack

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· **Packing group** · **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
56-40-6 glycine

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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Trade name: D-100 HbA1c Analytical Cartridge/Calibrator Pack

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

1 Identification

· **Product identifier**

· **Trade name: D-100 HbA1c Calibrator Pack**

· **Catalog or product number:** 2901006, 12008596
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable
· **Classification system**
· **Special Hazards** Contains human sourced and/or potentially infectious components.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Not applicable.
· **Additional information**
Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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Trade name: D-100 HbA1c Calibrator Pack

(Contd. of page 1)

· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

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Trade name: D-100 HbA1c Calibrator Pack

(Contd. of page 2)

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Color:	Pink
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.

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Trade name: D-100 HbA1c Calibrator Pack

(Contd. of page 3)

· **Solubility in / Miscibility with Water:**	Soluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Solids content:	100.0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values for hazardous components per OSHA criteria:**

56-40-6 glycine

Oral	LD50	7,930 mg/kg (rat)
Dermal	LD50	5,200 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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Trade name: D-100 HbA1c Calibrator Pack

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· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.
· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated

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Trade name: D-100 HbA1c Calibrator Pack

(Contd. of page 5)

· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

56-40-6	glycine	ACTIVE
6138-23-4	d-trehalose dihydrate	ACTIVE

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

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Trade name: D-100 HbA1c Calibrator Pack

(Contd. of page 6)

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· ***** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

1 Identification

· **Product identifier**

· **Trade name: D-100 HbA1c Elution Buffer A**

· **Catalog or product number:** 2901010, 12008592
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Not applicable.
· **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

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Trade name: D-100 HbA1c Elution Buffer A

(Contd. of page 1)

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** No special measures required.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 HbA1c Elution Buffer A

(Contd. of page 2)

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	6
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not determined.

(Contd. on page 4)

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acc. to OSHA HCS

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Trade name: D-100 HbA1c Elution Buffer A

(Contd. of page 3)

· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic at 20 °C:	0.952 mPas
kinematic:	Not determined.
· **Solvent content:**	
Water:	99.0 %
Solids content:	0.5 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

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Trade name: D-100 HbA1c Elution Buffer A

(Contd. of page 4)

· **Target organs:** Not applicable.

*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
Perchlorate material - special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

*
14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No

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Safety Data Sheet
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Trade name: D-100 HbA1c Elution Buffer A

(Contd. of page 5)

· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7732-18-5	water	ACTIVE
7601-89-0	sodium perchlorate	ACTIVE
110-15-6	succinic acid	ACTIVE
26628-22-8	sodium azide	ACTIVE

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

(Contd. on page 7)

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Trade name: D-100 HbA1c Elution Buffer A

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

1 Identification

· **Product identifier**

· **Trade name: D-100 HbA1c Elution Buffer B**

· **Catalog or product number:** 2901011, 12008593
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable

*

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

7601-89-0	sodium perchlorate	Ox. Sol. 1, H271 Acute Tox. 4, H302	1-2.5%

· **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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Trade name: D-100 HbA1c Elution Buffer B

(Contd. of page 1)

· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** No special measures required.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**		
sodium perchlorate		6.3 mg/m³
· **PAC-2:**		
7601-89-0	sodium perchlorate	69 mg/m³
· **PAC-3:**		
7601-89-0	sodium perchlorate	420 mg/m³

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 HbA1c Elution Buffer B

(Contd. of page 2)

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	7
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not determined.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 HbA1c Elution Buffer B

(Contd. of page 3)

· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic at 20 °C:	0.952 mPas
kinematic:	Not determined.
· **Solvent content:**	
Water:	98.1 %
Solids content:	1.1 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

(Contd. on page 5)

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Trade name: D-100 HbA1c Elution Buffer B

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· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
Perchlorate material - special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 HbA1c Elution Buffer B

(Contd. of page 5)

· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7732-18-5	water	ACTIVE
7601-89-0	sodium perchlorate	ACTIVE
26628-22-8	sodium azide	ACTIVE
110-15-6	succinic acid	ACTIVE

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

7601-89-0	sodium perchlorate	NL

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Trade name: D-100 HbA1c Elution Buffer B

(Contd. of page 6)

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Ox. Sol. 1: Oxidizing solids – Category 1
Acute Tox. 4: Acute toxicity – Category 4
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

1 Identification

· **Product identifier**

· **Trade name: D-100 Prefilter**

· **Catalog or product number:** 2901007, 12009090
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Not applicable.
· **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Prefilter

(Contd. of page 1)

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** No special measures required.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Prefilter

(Contd. of page 2)

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Color:	Green
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Prefilter

(Contd. of page 3)

· **Solubility in / Miscibility with Water:**	Insoluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Water:	50.0 %
Solids content:	50.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Prefilter

(Contd. of page 4)

· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 *Reviewed on 09/18/2020*

Trade name: D-100 Prefilter

(Contd. of page 5)

· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7732-18-5	water	ACTIVE
26628-22-8	sodium azide	ACTIVE

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Trade name: D-100 Prefilter

(Contd. of page 6)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

1 Identification

· **Product identifier**

· **Trade name: D-100 Wash Solution**

· **Catalog or product number:** 2901012, 12008594
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Not applicable.
· **Additional information** For the wording of the listed risk phrases refer to section 15.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Wash Solution

(Contd. of page 1)

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Dilute with plenty of water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 *Reviewed on 09/18/2020*

Trade name: D-100 Wash Solution

(Contd. of page 2)

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	6
· **Change in condition**	
Melting point/Melting range:	0 °C
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density at 20 °C:**	1.00005 g/cm³
· **Relative density**	Not determined.
· **Vapor density**	Not determined.

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Trade name: D-100 Wash Solution

(Contd. of page 3)

· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic at 20 °C:	0.952 mPas
kinematic:	Not determined.
· **Solvent content:**	
Water:	100.0 %
Solids content:	0.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

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Trade name: D-100 Wash Solution

(Contd. of page 4)

· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No

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Trade name: D-100 Wash Solution

(Contd. of page 5)

· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
All components have the value ACTIVE.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

(Contd. on page 7)

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acc. to OSHA HCS

Trade name: D-100 Wash Solution

(Contd. of page 6)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· *** Data compared to the previous version altered.**

Kit SDS Cover Sheet

Doc. ID: 33710-75: Rev. AH
Revised (year/month/day) 2015/04/21

Product Information

Product Name	DIGOXIN
Part Number	33710
Series Name	ACCESS®

Components

Description

Digoxin Particles (Compartment R1a)
Digoxin Conjugate (Compartment R1b)
Digoxin Antibody (Compartment R1c)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33710-75 Rev. AH
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Digoxin Particles (Compartment R1a)

Part Number Component of P/N 33710

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33710-75 Rev. AH
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Digoxin Conjugate (Compartment R1b)

Part Number Component of P/N 33710

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Global SDS – English

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: 33710-75 Rev. AH
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Digoxin Antibody (Compartment R1c)

Part Number Component of P/N 33710

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Global SDS – English

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Dip&Spin® Urinalysis Dipstick / Microscopics Control Level 1

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 21/12/2015 Date of issue: 21/12/2015 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Dip&Spin® Urinalysis Dipstick / Microscopics Control

Product Code: 1470-01

1.2. Intended Use of the Product

Laboratory Quality Control Material. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
310-536-0006
www.quantimetrix.com

1.4. Emergency Telephone Number

Emergency Number : 310-536-0006

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Skin Sens. 1 H317

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

GHS07

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US) : P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixture

Name	Product Identifier	% (w/w)	GHS-US classification
1,2-Propylene glycol	(CAS No) 57-55-6	5	Not classified
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	(CAS No) 55965-84-9	0.003	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311

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			Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause an allergic reaction in sensitive individuals.

Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Eye Contact: May cause eye irritation.

Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

Chronic Symptoms: None expected under anticipated conditions of normal use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Exercise caution when fighting any chemical fire.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing vapor, mist, or spray. Avoid contact with skin, eyes, or clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Absorb and/or contain spill with inert material, then place in suitable container.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Laboratory Quality Control Material. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

1,2-Propylene glycol (57-55-6)		
USA AIHA	WEEL TWA (mg/m³)	10 mg/m³
Ontario	OEL TWA (mg/m³)	10 mg/m³ (for assessing the visibility in a work environment where 1,2-Propylene glycol aerosol is present-aerosol only) 155 mg/m³ (aerosol and vapor)
Ontario	OEL TWA (ppm)	50 ppm (aerosol and vapor)

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Gloves. Protective clothing.

Materials for Protective Clothing: Chemically resistant fabrics and materials.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: None required under normal conditions of use.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Amber Yellow

Odor : Odorless

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Odor Threshold	:	Not available
pH	:	6
Evaporation Rate	:	Not available
Melting Point	:	Not available
Freezing Point	:	Not available
Boiling Point	:	Not available
Flash Point	:	Not available
Auto-ignition Temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not available
Lower Flammable Limit	:	Not available
Upper Flammable Limit	:	Not available
Vapor Pressure	:	Not available
Relative Vapor Density at 20 °C	:	Not available
Specific Gravity	:	1
Solubility	:	Not available
Partition Coefficient: N-Octanol/Water	:	Not available
Viscosity	:	Not available
Explosion Data – Sensitivity to Mechanical Impact	:	Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge	:	Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Product is stable.

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous Decomposition Products: The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/Injuries After Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

Chronic Symptoms: None expected under anticipated conditions of normal use.

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11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

1,2-Propylene glycol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
LD50 Oral Rat	53 mg/kg
ATE US (oral)	53.00 mg/kg body weight
ATE US (dermal)	300.00 mg/kg body weight
ATE US (dust, mist)	0.50 mg/l/4h

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity No additional information available

1,2-Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC 50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and Degradability

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 1	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 1	
Bioaccumulative Potential	Not established.

1,2-Propylene glycol (57-55-6)	
BCF Fish 1	< 1
Log Pow	-0.92

12.4. Mobility in Soil

Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

1,2-Propylene glycol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

15.2. US State Regulations

1,2-Propylene glycol (57-55-6)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

15.3. Canadian Regulations

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 1	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

1,2-Propylene glycol (57-55-6)	
Listed on the Canadian DSL (Domestic Substances List) Listed on the Canadian IDL (Ingredient Disclosure List)	
IDL Concentration 1 %	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
Listed on the Canadian DSL (Domestic Substances List)	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects Class E - Corrosive Material Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 11/24/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction

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H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Party Responsible for the Preparation of This Document

Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
310-536-0006

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS

Dip&Spin® Urinalysis Dipstick / Microscopics Control Level 2

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 12/21/2015 Date of issue: 12/21/2015 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Dip&Spin® Urinalysis Dipstick / Microscopics Control, Level 2

Product Code: 1470-01

1.2. Intended Use of the Product

Laboratory Quality Control Material. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
310-536-0006
www.quantimetrix.com

1.4. Emergency Telephone Number

Emergency Number : 310-536-0006

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Skin Sens. 1 H317

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

GHS07

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US) : P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixture

Name	Product Identifier	% (w/w)	GHS-US classification
2,4-Pentanedione	(CAS No) 123-54-6	0.11	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311

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			Acute Tox. 3 (Inhalation:vapour), H331 Aquatic Acute 3, H402
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	(CAS No) 55965-84-9	0.003	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause an allergic reaction in sensitive individuals.

Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Eye Contact: May cause eye irritation.

Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

Chronic Symptoms: None expected under anticipated conditions of normal use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Exercise caution when fighting any chemical fire.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing vapor, mist, or spray. Avoid contact with skin, eyes, or clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area.

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6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Absorb and/or contain spill with inert material, then place in suitable container.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Laboratory Quality Control Material. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

2,4-Pentanedione (123-54-6)		
USA ACGIH	ACGIH TWA (ppm)	25 ppm
USA ACGIH	ACGIH chemical category	Skin - potential significant contribution to overall exposure by the cutaneous route
Manitoba	OEL TWA (ppm)	25 ppm
Newfoundland & Labrador	OEL TWA (ppm)	25 ppm
Nova Scotia	OEL TWA (ppm)	25 ppm
Ontario	OEL TWA (ppm)	25 ppm
Prince Edward Island	OEL TWA (ppm)	25 ppm

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing.

Materials for Protective Clothing: Chemically resistant fabrics and materials.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Amber Yellow

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Odor	:	Odorless
Odor Threshold	:	Not available
pH	:	6
Evaporation Rate	:	Not available
Melting Point	:	Not available
Freezing Point	:	Not available
Boiling Point	:	Not available
Flash Point	:	Not available
Auto-ignition Temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not available
Lower Flammable Limit	:	Not available
Upper Flammable Limit	:	Not available
Vapor Pressure	:	Not available
Relative Vapor Density at 20 °C	:	Not available
Specific Gravity	:	1
Solubility	:	Not available
Partition Coefficient: N-Octanol/Water	:	Not available
Viscosity	:	Not available
Explosion Data – Sensitivity to Mechanical Impact	:	Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge	:	Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Product is stable.

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous Decomposition Products: The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/Injuries After Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

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Chronic Symptoms: None expected under anticipated conditions of normal use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
LD50 Oral Rat	53 mg/kg
ATE US (oral)	53.00 mg/kg body weight
ATE US (dermal)	300.00 mg/kg body weight
ATE US (dust, mist)	0.50 mg/l/4h

2,4-Pentanedione (123-54-6)	
LD50 Oral Rat	760 mg/kg
LD50 Dermal Rabbit	770 mg/kg
LC50 Inhalation Rat	5.01 mg/l/4h
LC50 Inhalation Rat	1224 ppm/4h

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

2,4-Pentanedione (123-54-6)	
LC50 Fish 1	98.3 - 110 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	34.4 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	50.3 - 71.8 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])

12.2. Persistence and Degradability

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 2	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 2	
Bioaccumulative Potential	Not established.

2,4-Pentanedione (123-54-6)	
Log Pow	0.34

12.4. Mobility in Soil Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

2,4-Pentanedione (123-54-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	S - S - indicates a substance that is identified in a proposed or final Significant New Uses Rule.

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15.2. US State Regulations

2,4-Pentanedione (123-54-6)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

15.3. Canadian Regulations

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 2	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

2,4-Pentanedione (123-54-6)	
Listed on the Canadian DSL (Domestic Substances List) Listed on the Canadian IDL (Ingredient Disclosure List)	
IDL Concentration 1 %	
WHMIS Classification	Class B Division 2 - Flammable Liquid Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects Class D Division 1 Subdivision A - Very toxic material causing immediate and serious toxic effects

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
Listed on the Canadian DSL (Domestic Substances List)	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects Class E - Corrosive Material Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 11/24/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1

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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Party Responsible for the Preparation of This Document

Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
310-536-0006

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS

Kit SDS Cover Sheet

Doc. ID: A79783-75: Rev. AE
Revised (year/month/day) 2015/04/21

Product Information

Product Name	Access SAMPLE DILUENT A
Part Number	A79783
Series Name	ACCESS

Components

Description

Sample Diluent A (Compartment R1a)
Sample Diluent A (Compartment R1b)
Sample Diluent A (Compartment R1c)
Sample Diluent A (Compartment R1d)
Sample Diluent A (Compartment R1e)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79783-75 Rev. AE
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Diluent A (Compartment R1a)

Part Number A79783

Series Name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pale yellow; Clear; Liquid; Slight odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated alkyl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.2.5% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

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Section 3 Composition and Information on Ingredients (Continued)

Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	No	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.035 @20°C
Color	Pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79783-75 Rev. AE
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Diluent A (Compartment R1b)

Part Number A79783

Series Name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pale yellow; Clear; Liquid; Slight odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated alkyl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.2.5% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

Section 3 Composition and Information on Ingredients (Continued)

Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	No	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.035 @20°C
Color	Pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Global SDS – English

Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79783-75 Rev. AE
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Diluent A (Compartment R1c)

Part Number A79783

Series Name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
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Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pale yellow; Clear; Liquid; Slight odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated alkyl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.2.5% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

Section 3 Composition and Information on Ingredients (Continued)

Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	No	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.035 @20°C
Color	Pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79783-75 Rev. AE
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Diluent A (Compartment R1d)

Part Number A79783

Series Name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pale yellow; Clear; Liquid; Slight odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated alkyl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.2.5% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

Section 3 Composition and Information on Ingredients (Continued)

Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	No	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.035 @20°C
Color	Pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Global SDS – English

Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79783-75 Rev. AE
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Diluent A (Compartment R1e)

Part Number A79783

Series Name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pale yellow; Clear; Liquid; Slight odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated alkyl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.2.5% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

Section 3 Composition and Information on Ingredients (Continued)

Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	No	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.035 @20°C
Color	Pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: A79784-75: Rev. AF
Revised (year/month/day) 2018/01/15

Product Information

Product Name	UniCel DxI Access Immunoassay Systems Wash Buffer II
Part Number	A79784
Series Name	ACCESS

Components

Description

Wash Buffer II (Compartment R1a)
Wash Buffer II (Compartment R1b)
Wash Buffer II (Compartment R1c)
Wash Buffer II (Compartment R1d)
Wash Buffer II (Compartment R1e)

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: A79784-75 Rev. AF
Revised (year/month/day) 2018/01/15

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Wash Buffer II (Compartment R1a)

Part Number A79784

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless to pale yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.006 @20°C
Color	Colorless to pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.31 @25°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.	
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.
Propylene Glycol is listed.

Pennsylvania RTK

Sodium Azide is listed.
Propylene Glycol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide
Propylene Glycol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 3, 4, 8, 11, 14, 15, 16.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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SAFETY DATA SHEET

Doc. ID: A79784-75 Rev. AF
Revised (year/month/day) 2018/01/15

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Wash Buffer II (Compartment R1b)

Part Number A79784

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless to pale yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.006 @20°C
Color	Colorless to pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.31 @25°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.	
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.
Propylene Glycol is listed.

Pennsylvania RTK

Sodium Azide is listed.
Propylene Glycol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide
Propylene Glycol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 3, 4, 8, 11, 14, 15, 16.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79784-75 Rev. AF
Revised (year/month/day) 2018/01/15

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Wash Buffer II (Compartment R1c)

Part Number A79784

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless to pale yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.006 @20°C
Color	Colorless to pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.31 @25°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.	
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.
Propylene Glycol is listed.

Pennsylvania RTK

Sodium Azide is listed.
Propylene Glycol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide
Propylene Glycol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 3, 4, 8, 11, 14, 15, 16.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79784-75 Rev. AF
Revised (year/month/day) 2018/01/15

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Wash Buffer II (Compartment R1d)

Part Number A79784

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless to pale yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.006 @20°C
Color	Colorless to pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.31 @25°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.	
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.
Propylene Glycol is listed.

Pennsylvania RTK

Sodium Azide is listed.
Propylene Glycol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide
Propylene Glycol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 3, 4, 8, 11, 14, 15, 16.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A79784-75 Rev. AF
Revised (year/month/day) 2018/01/15

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Wash Buffer II (Compartment R1e)

Part Number A79784

Series Name ACCESS

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless to pale yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.006 @20°C
Color	Colorless to pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.31 @25°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.	
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.
Propylene Glycol is listed.

Pennsylvania RTK

Sodium Azide is listed.
Propylene Glycol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide
Propylene Glycol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 3, 4, 8, 11, 14, 15, 16.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 628017-75 Rev. AG
Revised (year/month/day) 2016/01/06

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Coulter® DxH Diluent

Part Number 628017

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Imidazole

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.

H316 Causes mild skin irritation.

EUH208 May produce an allergic reaction.

Precautionary Statements

P201 Obtain special instructions before use.

P280 Wear protective gloves, protective clothing and eye/face protection.

P501 Dispose of contents/container in accordance with local/national regulations

P332+P313 If skin irritation occurs: Get medical advice/attention.

P405 Store locked up.

P308+P313 IF exposed or concerned: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Imidazole CAS # 288-32-4 EINECS # 206-019-2 Index # Not available	< 1	Xn;R22 C;R34	Acute Tox. Oral 4 Repr. 1B Skin Corr. 1C H302; H314; H360	Acute Tox. Oral 4 Repr. 1B Skin Corr. 1C H302; H314; H360	

Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	15, 8

15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

May damage fertility or the unborn child.

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 40°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

DFG MAK None established

Ireland None established

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Section 8 Exposure Controls and Personal Protection (Continued)

	IOELVs	None established
	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0 - 7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity — No further relevant information available.

10.2 Chemical Stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid — To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Imidazole CAS # 288-32-4	Oral LD50 Rat 220 mg/kg

Primary Routes of Exposure — Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation — Causes mild skin irritation.

Serious eye damage/eye irritation — No data available.

Respiratory/skin sensitization — This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity — No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity — No data available.

Reproductive Toxicity — May damage fertility or the unborn child.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	
Imidazole CAS # 288-32-4	48 h EC50 Daphnia magna: 341.5 mg/L
Fresh Water Algae	
Imidazole CAS # 288-32-4	72 h EC50 Desmodesmus subspicatus: 130 mg/L; 96 h EC50 Desmodesmus subspicatus: 82 mg/L

12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.
12.5 Results of PBT and vPvB assessment	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6 Other Adverse Effects	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
13.2 Additional information	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA, IMDG, US DOT, European ADR and RID or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	Hydrochloric Acid is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration (acid
CERCLA RG's, 40 CFR 302.4	Hydrochloric Acid is listed.
California Proposition 65	No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Trisodium Nitrilotriacetate is listed.
Hydrochloric Acid is listed.
Sodium Sulfate is listed.
Magnesium Nitrate is listed.

New Jersey Dept. of Health RTK List

Hydrochloric Acid is listed.
Magnesium Nitrate is listed.

Pennsylvania RTK
Hydrochloric Acid is listed.
Sodium Sulfate is listed.
Magnesium Nitrate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Hydrochloric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes
Updated Section 2.
Updated Section 3.
Updated Section 11.
Revised Beckman Coulter safety rating.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
N - Dangerous for the environment

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Section 16 Other Information (Continued)

T - Toxic
Xn - Harmful
R22 Harmful if swallowed.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1 - Skin Sensitization Category 1
Repr. 1B - Toxic to Reproductive Category 1B
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration

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Section 16 Other Information (Continued)

PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Doc. ID: 33540-75: Rev. AH
Revised (year/month/day) 2015/04/15

Product Information

Product Name	Estradiol
Part Number	33540
Series Name	ACCESS®

Components

Description

Estradiol Particles (Compartment R1a)
Estradiol Blocker (Compartment R1b)
Estradiol Conjugate (Compartment R1c)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 33540-75 Rev. AH
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Estradiol Particles (Compartment R1a)

Part Number Component of P/N 33540

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.8	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: 33540-75 Rev. AH
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Estradiol Blocker (Compartment R1b)

Part Number Component of P/N 33540

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0436 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.8	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Danazol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Mesterolone has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Danazol is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Global SDS – English

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33540-75 Rev. AH
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Estradiol Conjugate (Compartment R1c)

Part Number Component of P/N 33540

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.8	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Estradiol has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Estradiol is listed.
Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Estradiol is listed.
Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.

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Section 16 Other Information (Continued)

	R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: 33020-75: Rev. AH
Revised (year/month/day) 2015/03/31

Product Information

Product Name	FERRITIN
Part Number	33020
Series Name	ACCESS®

Components

Description	Ferritin Particles (Well R1a) Ferritin Conjugate (Well R1b)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33020-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Ferritin Particles (Well R1a)

Part Number Component of P/N 33020

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Reddish-brown when particles suspended; Opaque; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Matrix is miscible
Odor	Mild odor	**Organic**	Not determined
pH	8.0	**Partition coefficient: n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

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Section 16 Other Information (Continued)

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33020-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Ferritin Conjugate (Well R1b)

Part Number Component of P/N 33020

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Translucent; Liquid; Musty

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01
Color	Colorless	**Solubility**	
Transparency	Translucent	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Musty	**Organic**	Not determined
pH	8.0 @23°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.

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Section 16 Other Information (Continued)

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Doc. ID: A98032-75: Rev. AE
Revised (year/month/day) 2015/03/20

Product Information

Product Name	Access® FOLATE
Part Number	A98032
Series Name	ACCESS®

Components

Description

Folate PMP (Compartment R1a)
Folate Ascorbate (Compartment R1b)
Folate Binding Protein (Compartment R1c)
Folate Conjugate (Compartment R1d)
Folate Phosphate (Compartment R1e)

Transport Information

Shipping Information	**IATA**	**IMDG**	**US DOT**	**European ADR**	**Canadian TDG**
UN/ID Number	3316	3316	3316	3316	3316
Shipping Name	Chemical kit				
Hazard Class	9 Miscellaneous Dangerous Goods	9 Miscellaneous dangerous substances and articles	9 Miscellaneous hazardous material	9 Miscellaneous dangerous substances and articles	9 Miscellaneous Dangerous Goods
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	M11	Not applicable
Packing Group	II	II	II	II	II
Special Provisions	A44; A163; A802	251; 340	15	251	65
Additional information					
IATA ERG Code	9L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-P	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	171	Not applicable	171
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A98032-75 Rev. AE
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Folate PMP (Compartment R1a)

Part Number Component of P/N A98032

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Reddish-brown; Opaque; Liquid - Suspension; Musty

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Borate Decahydrate

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

DANGER

Hazard Statements

H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.
May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard Classification of Pure Ingredients

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Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Borate Decahydrate CAS # 1303-96-4 EINECS # 237-560-2 Index # 005-011-01-1	1 - 2	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause sensitization by skin contact.
May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media For large fires use extinguishing media suitable for surrounding fire.
In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.
This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain efficacy, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Borate Decahydrate CAS # 1303-96-4	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid - Suspension	**Specific Gravity (Water=1.0)**	1.014
Color	Reddish-brown	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Musty	**Organic**	Not determined
pH	7.4 @23°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Borate Decahydrate CAS # 1303-96-4	Oral LD50 Rat 2660 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation

Causes mild skin irritation.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

May cause sensitization by skin contact.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

Reproductive effects have been reported in animal studies.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Borate Decahydrate is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Sodium Borate Decahydrate
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Global SDS – English

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Repr. Cat. 2 - Toxic for Reproduction Category 2
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 May impair fertility.
R61 May cause harm to unborn child.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 3 - Skin Irritation Category 3
Skin Sens. 1 - Skin Sensitization Category 1
Repr. 1B - Toxic to Reproductive Category 1B
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H303 - May be harmful if swallowed
H311 - Toxic in contact with skin.
H313 - May be harmful In contact with skin
H314 - Causes severe skin burns and eye damage.
H316 - Causes mild skin irritation.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A98032-75 Rev. AE
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Folate Ascorbate (Compartment R1b)

Part Number Component of P/N A98032

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.099
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	5.5 @23°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		No further relevant information available.
10.4	**Conditions to Avoid**	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing significant hazards would be expected from this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard	No data available.
Other Information	No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - Internal Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

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Access® FOLATE
Folate Ascorbate (Compartment R1b)

SAFETY DATA SHEET

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Section 16 Other Information (Continued)

NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A98032-75 Rev. AE
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Folate Binding Protein (Compartment R1c)

Part Number Component of P/N A98032

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Colorless; Translucent; Liquid; Musty

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Borate Decahydrate

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

DANGER

Hazard Statements

H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.
May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard Classification of Pure Ingredients

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Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Borate Decahydrate CAS # 1303-96-4 EINECS # 237-560-2 Index # 005-011-01-1	1 - 2	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause sensitization by skin contact.
May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media For large fires use extinguishing media suitable for surrounding fire.
In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.
This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain efficacy, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Borate Decahydrate CAS # 1303-96-4	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.014
Color	Colorless	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Musty	**Organic**	Not determined
pH	7.4 @23°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Borate Decahydrate CAS # 1303-96-4	Oral LD50 Rat 2660 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation

Causes mild skin irritation.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

May cause sensitization by skin contact.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

Reproductive effects have been reported in animal studies.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Borate Decahydrate is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Borate Decahydrate is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Sodium Borate Decahydrate
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Global SDS – English

BECKMAN COULTER
Access® FOLATE
Folate Binding Protein (Compartment R1c)

SAFETY DATA SHEET
Doc. ID: A98032-75 Rev. AE
Revised (year/month/day) 2015/03/20

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Repr. Cat. 2 - Toxic for Reproduction Category 2
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 May impair fertility.
R61 May cause harm to unborn child.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 3 - Skin Irritation Category 3
Skin Sens. 1 - Skin Sensitization Category 1
Repr. 1B - Toxic to Reproductive Category 1B
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H303 - May be harmful if swallowed
H311 - Toxic in contact with skin.
H313 - May be harmful In contact with skin
H314 - Causes severe skin burns and eye damage.
H316 - Causes mild skin irritation.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A98032-75 Rev. AE
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Folate Conjugate (Compartment R1d)

Part Number Component of P/N A98032

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Colorless; Translucent; Liquid; Musty

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

Product label will display most significant precautionary statements.

May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	15, 8, 9

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Section 3 Composition and Information on Ingredients (Continued)

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

For large fires use extinguishing media suitable for surrounding fire.

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear protective gloves, protective clothing and eye/face protection.

Observe general safety guidelines for protection; avoid eye and skin contact.

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain efficacy, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.014
Color	Colorless	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Musty	**Organic**	Not determined
pH	8.05 @23°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause an allergic skin reaction.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A98032-75 Rev. AE
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Folate Phosphate (Compartment R1e)

Part Number Component of P/N A98032

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R36/38

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1

Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

Potential Health Effects Summary

Corrosive. May cause burns to eyes, skin and respiratory tract.

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Potassium Phosphate, Tribasic

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

Potassium Phosphate, Tribasic CAS # 7778-53-2 EINECS # 231-907-1 Index # Not available	10 - 15	Xi;R36/38	Eye Dam. 1 Skin Irrit. 2 H315; H318	Acute Tox. Dermal 5 Acute Tox. Oral 5 Eye Dam. 1 Skin Irrit. 2 H303; H313; H315; H318	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

Corrosive. May cause burns to eyes, skin and respiratory tract.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Avoid contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.105
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	12.3 @23°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Potassium Phosphate, Tribasic CAS # 7778-53-2	Oral LD50 Rat 2000 mg/kg; Dermal LD50 Rabbit >4640 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation Causes severe skin burns.

Serious eye damage/eye irritation Causes serious eye damage.

Respiratory/skin sensitization No data available.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	**UN/ID Number**	3266	3266	3266	3266	PIN - 3266
14.2	**Shipping Name**	Corrosive liquid, basic, inorganic, n.o.s. (Potassium phosphate, tribasic solution)				
14.3	**Hazard Class**	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	**Packing Group**	III	III	III	III	III
	Special Provisions	None	274	Not applicable	274	Not applicable
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable

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Section 14 Transport Information (Continued)

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5 Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R36/38 Irritating to eyes and skin.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37 Wear suitable gloves.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 3266

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Global SDS – English

Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

Xi - Irritant
R36/38 Irritating to eyes and skin.
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Eye Dam. 1 - Eye Damage Category 1
Skin Irrit. 2 - Skin Irritation Category 2
H303 - May be harmful if swallowed
H313 - May be harmful In contact with skin
H315 - Causes skin irritation.
H318 - Causes serious eye damage.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program

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Section 16 Other Information (Continued)

OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: 33880-75: Rev. AH
Revised (year/month/day) 2015/03/31

Product Information

Product Name	Free T4
Part Number	33880
Series Name	ACCESS®

Components

Description

PMP (Compartment R1a)
Buffer 1 (Compartment R1b)
Buffer 2 (Compartment R1c)
Conjugate (Compartment R1d)
Biotin Reagent (Compartment R1e)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33880-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PMP (Compartment R1a)

Part Number Component of P/N 33880

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22-43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.18	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0109 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	7.91	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Global SDS – English

Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases
R22 Harmful if swallowed.
R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3
N - Dangerous for the environment
T - Toxic

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Section 16 Other Information (Continued)

T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act

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Section 16 Other Information (Continued)

TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33880-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Buffer 1 (Compartment R1b)

Part Number Component of P/N 33880

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0086 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	8.3	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic

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Section 16 Other Information (Continued)

T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act

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Global SDS – English

Section 16 Other Information (Continued)

TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33880-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Buffer 2 (Compartment R1c)

Part Number Component of P/N 33880

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22-43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.18	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0967 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	7.91	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

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Section 15 Regulatory Information (Continued)

PIN Not applicable

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Polyoxyethylated Octyl Phenol
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33880-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Conjugate (Compartment R1d)

Part Number Component of P/N 33880

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0116 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	5.96	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.

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Section 16 Other Information (Continued)

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33880-75 Rev. AH
Revised (year/month/day) 2015/03/31

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Biotin Reagent (Compartment R1e)

Part Number Component of P/N 33880

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22-43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.18	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0109 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	7.91	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.

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Section 16 Other Information (Continued)

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: IM2125-75: Rev. AA
Issued (year/month/day) 2015/04/16

Product Information

Product Name FSH IRMA

Part Number IM2125

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Tracer
Calibrators
Control
Wash Solution (20X)

Transport Information

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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SAFETY DATA SHEET

Doc. ID: IM2125-75 Rev. AA
Issued (year/month/day) 2015/04/16

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Tracer

Part Number Component of P/N IM2125

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Blue; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Boric Acid

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.

P280 Wear protective gloves, protective clothing and eye/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard Classification of Pure Ingredients

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Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Boric Acid CAS # 10043-35-3 EINECS # 233-139-2 Index # Not available	1 - 2	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Radioactive material is subject to the regulations of each country.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Boric Acid CAS # 10043-35-3	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Boric Acid CAS # 10043-35-3	10 mg/m3 Peak (as B) (inhalable fraction); 10 mg/m3 TWA MAK (inhalable fraction) (as B)
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0 @20°C

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Section 9 Physical and Chemical Properties (Continued)

	Color	Blue	**Solubility**	
	Transparency	Clear	**Water**	Miscible
	Odor	Odorless	**Organic**	Not determined
	pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Boric Acid CAS # 10043-35-3	Oral LD50 Rat 2660 mg/kg; Inhalation LC50 Rat >0.16 mg/L 4 h; Dermal LD50 Rabbit >2000 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Microtox No information available.

Water Flea

Boric Acid CAS # 10043-35-3	48 h EC50 Daphnia magna: 115 - 153 mg/L

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

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Section 12 Ecological Information (Continued)

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	2910	2910	2910	2910	PIN - 2910
14.2	Shipping Name	Radioactive Material, excepted package-limited quantity of material				
14.3	Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
14.4	Packing Group					

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Section 14 Transport Information (Continued)

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Iodine 125 has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 2910

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Boric Acid
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Repr. Cat. 2 - Toxic for Reproduction Category 2
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 May impair fertility.
R61 May cause harm to unborn child.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5

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Section 16 Other Information (Continued)

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 3 - Skin Irritation Category 3
Repr. 1B - Toxic to Reproductive Category 1B
H300 - Fatal if swallowed.
H303 - May be harmful if swallowed
H313 - May be harmful In contact with skin
H316 - Causes mild skin irritation.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2125-75 Rev. AA
Issued (year/month/day) 2015/04/16

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Calibrators

Part Number Component of P/N IM2125

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Global SDS – English

Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2125-75 Rev. AA
Issued (year/month/day) 2015/04/16

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Control

Part Number Component of P/N IM2125

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Lyophilized Powder - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.00 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Global SDS – English

Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2125-75 Rev. AA
Issued (year/month/day) 2015/04/16

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Wash Solution (20X)

Part Number Component of P/N IM2125

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Boric Acid
Sodium Borate Decahydrate

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations
Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Borate Decahydrate CAS # 1303-96-4 EINECS # 237-560-2 Index # 005-011-01-1	0.1-0.3	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
Boric Acid CAS # 10043-35-3 EINECS # 233-139-2 Index # Not available	0.1-0.3	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC

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Section 3 Composition and Information on Ingredients (Continued)

SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.
Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Borate Decahydrate CAS # 1303-96-4	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)
Boric Acid CAS # 10043-35-3	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)

DFG MAK

Boric Acid CAS # 10043-35-3	10 mg/m3 Peak (as B) (inhalable fraction); 10 mg/m3 TWA MAK (inhalable fraction) (as B)

Ireland

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA

IOELVs

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

NIOSH

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.3	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Borate Decahydrate CAS # 1303-96-4	Oral LD50 Rat 2660 mg/kg
Boric Acid CAS # 10043-35-3	Oral LD50 Rat 2660 mg/kg; Inhalation LC50 Rat >0.16 mg/L 4 h; Dermal LD50 Rabbit >2000 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	May damage fertility or the unborn child.
Specific target organ toxicity – single exposure	No data available.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

Microtox No information available.

Water Flea

Boric Acid
CAS # 10043-35-3 — 48 h EC50 Daphnia magna: 115 - 153 mg/L

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Borate Decahydrate is listed.

New Jersey Dept. of Health RTK List

Sodium Borate Decahydrate is listed.

Pennsylvania RTK Sodium Borate Decahydrate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Borate Decahydrate
Boric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

T - Toxic
Repr. Cat. 2 - Toxic for Reproduction Category 2

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Section 16 Other Information (Continued)

	R60 May impair fertility. R61 May cause harm to unborn child. Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5 Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5 Skin Irrit. 3 - Skin Irritation Category 3 Repr. 1B - Toxic to Reproductive Category 1B H303 - May be harmful if swallowed H313 - May be harmful In contact with skin H316 - Causes mild skin irritation. H360 - May damage fertility or the unborn child.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Document ID: OSR6121-75: Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Product Information

Product Name	Glucose Glucose STAT
Part Number	OSR6121, OSR6221, OSR6621

Components

Description	Glucose R1, Glucose STAT Component 1 Glucose R2, Glucose STAT Component 2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: OSR6121-75 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Glucose R1, Glucose STAT Component 1

Part Number Component of P/N OSR6121, OSR6221, OSR6621

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light yellow; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements — **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	7.6 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

Microtox No information available.

Water Flea No information available.

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Section 12 Ecological Information (Continued)

	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

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14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

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Section 15 Regulatory Information (Continued)

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated part numbers.
Updated E-mail address in Sec. 1.3.
Updated Section 8, 11, 15, 16.
Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08
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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health

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Section 16 Other Information (Continued)

NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Glucose R2, Glucose STAT Component 2

Part Number Component of P/N OSR6121, OSR6221, OSR6621

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.07
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.6 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated part numbers.
Updated E-mail address in Sec. 1.3.
Updated Section 8, 11, 15, 16.
Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08
Document ID: OSR6121-75
Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Issuing Date January 5, 2015 **Revision Date** New **Revision Number** 0

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name **Green Works® Glass & Surface Cleaner - 98% Naturally Derived**

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Multi-surface spray cleaner

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Address
The Clorox Company
1221 Broadway
Oakland, CA 94612

Phone: 1-510-271-7000

Emergency telephone number

Emergency Phone Numbers For Medical Emergencies call: 1-800-446-1014
For Transportation Emergencies, call Chemtrec: 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Appearance Clear, colorless **Physical State** Thin liquid **Odor** Fresh Lemon

Precautionary Statements - Prevention
None

Precautionary Statements - Response
None

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
None

Hazards not otherwise classified (HNOC)
Not applicable

Unknown Toxicity
0.6% of the mixture consists of ingredient(s) of unknown toxicity

Other information
May cause slight eye irritation.

Interactions with Other Chemicals
No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product contains no substances that at their given concentrations are considered to be hazardous to health.

4. FIRST AID MEASURES

First aid measures

General Advice Show this safety data sheet to the doctor in attendance.

Eye Contact Hold eye open and rinse slowly and gently with water for 15–20 minutes. If present, remove contact lenses after the first 5 minutes of rinsing, then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

Skin Contact Rinse skin with plenty of water. If irritation persists, call a doctor.

Inhalation Move to fresh air. If breathing problems develop, call a doctor.

Ingestion Drink a glassful of water. Call a doctor or poison control center.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects May cause slight eye irritation.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media
CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products
Oxides of carbon.

Explosion Data

Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with eyes.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental Precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Absorb and containerize. Wash residual down to sanitary sewer. Contact the sanitary treatment facility in advance to assure ability to process washed-down material.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes, skin, and clothing. Do not eat, drink, or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed.

Incompatible Products None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any ingredients with occupational exposure limits that are at concentrations below their cut-off values/concentrations and that contribute to the hazard classification of the product.

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection No special protective equipment required.

Skin and Body Protection No special protective equipment required.

Respiratory Protection No protective equipment is needed under normal use conditions. If irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical State	Thin liquid		
Appearance	Clear	**Odor**	Fresh lemon
Color	Colorless	**Odor Threshold**	No information available

Property	**Values**	**Remarks/ Method**
pH	10 - 11	None known
Melting/freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
Upper flammability limit	No data available	None known
Lower flammability limit	No data available	None known
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	~1.0	None known
Water Solubility	Complete	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive Properties	Not explosive	
Oxidizing Properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None known.

Conditions to avoid
None known.

Incompatible materials
None known.

Hazardous Decomposition Products
None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information .

Inhalation Exposure to vapor or mist may irritate respiratory tract.

Eye Contact May cause slight irritation.

Skin Contact May cause slight irritation.

Ingestion Ingestion of liquid may cause slight irritation to mucous membranes and gastrointestinal tract.

Information on toxicological effects

Symptoms May cause slight redness and tearing of eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethanol 64-17-5	A3	Group 1	Known	X

ACGIH (American Conference of Governmental Industrial Hygienists)
A3 - Animal Carcinogen
IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

Reproductive Toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity Contains a known or suspected carcinogen. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage. Contains a known or suspected reproductive toxin. Ethanol has been shown to be a reproductive toxin only when consumed as an alcoholic beverage. May cause adverse effects on the bone marrow and blood-forming system. May cause adverse liver effects. Repeated abuse can have long-term health effects.

Target Organ Effects Eyes, blood, central nervous system (CNS), liver, reproductive system, respiratory system.

Aspiration Hazard Not an aspiration hazard.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document
No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Ethanol 64-17-5		LC50: 12.0 - 16.0 mL/L (96 h static) Oncorhynchus mykiss LC50: 13400 - 15100 mg/L (96 h flow-through) Pimephales promelas LC50: > 100 mg/L (96 h static) Pimephales promelas	EC50 = 34634 mg/L 30 min EC50 = 35470 mg/L 5 min	LC50: 9268 - 14221 mg/L (48 h) Daphnia magna EC50: 10800 mg/L (24 h) Daphnia magna EC50: 2 mg/L (48 h Static) Daphnia magna

Persistence and Degradability
No information available.

Bioaccumulation

Chemical Name	Log Pow
Ethanol 64-17-5	-0.32

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods
Dispose of in accordance with all applicable federal, state, and local regulations.

Contaminated Packaging
Do not reuse empty containers. Dispose of in accordance with all applicable federal, state, and local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

ICAO Not regulated.

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

Chemical Inventories

TSCA	All components of this product are either on the TSCA 8(b) Inventory or otherwise exempt from listing.
DSL/NDSL	All components are on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals. Ethyl alcohol is only a considered a Proposition 65 developmental hazard when it is ingested as an alcoholic beverage.

Chemical Name	California Proposition 65
Ethanol 64-17-5	Developmental

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Ethanol 64-17-5		X			

International Regulations

Canada
WHMIS Hazard Class
Not controlled.

16. OTHER INFORMATION

NFPA	**Health Hazard**	0	**Flammability**	0	**Instability**	0	**Physical and Chemical Hazards** -
HMIS	**Health Hazard**	0	**Flammability**	0	**Physical Hazard**	0	**Personal Protection** -

Prepared By

Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Preparation/Revision Date January 5, 2015

Revision Note New

Reference 1096735/111857.001

General Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Kit SDS Cover Sheet

Doc. ID: OSR6187-75: Rev. 06
Revised (year/month/day) 2017/05/08

Product Information

Product Name	**HDL Cholesterol**
Part Number	OSR6187, OSR6287, OSR6687

Components

Description	HDL Cholesterol R1 HDL Cholesterol R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: OSR6187-75 Rev. 06
Revised (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name HDL Cholesterol R1

Part Number Component of P/N OSR6187, OSR6287, OSR6687

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation Not based on available data.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S60 This material and/or its container must be disposed of as hazardous waste.
S37 Wear suitable gloves.
S23 Do not breathe vapor.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated part numbers.
Updated section 4, 8, 11, 14, 15, 16.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

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Section 16 Other Information (Continued)

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: OSR6187-75 Rev. 06
Revised (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name HDL Cholesterol R2

Part Number Component of P/N OSR6187, OSR6287, OSR6687

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to EC Directives 1999/45/EC and 67/548/EEC

Not as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties aqueous solution.

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

DFG MAK None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

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Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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HDL Cholesterol
HDL Cholesterol R2

SAFETY DATA SHEET
Doc. ID: OSR6187-75 Rev. 06
Revised (year/month/day) 2017/05/08

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated part numbers. Updated Section 4, 8, 11, 14, 15.	

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Doc. ID: B29754 Rev. AD
Revised (year/month/day) 2015/07/24

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name UniCel DxC SYNCHRON Systems HDL Calibrator

Part Number B23634

Series Name UniCel® DxC Synchron® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Pale yellow; Clear; Lyophilized - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Aquatic Hazard Long term, Category 3

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22-52/53

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Azide

Pictogram

None

Signal Word

None

Hazard Statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains Sodium azide which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.5	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

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Section 4 First Aid Measures (Continued)

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions — Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Carefully sweep up spilled material and place in a container suitable for disposal. Avoid generating dust.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	≈1.00 @20°C
Color	Pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.5-7.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

This product contains Sodium azide which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

10.4 Conditions to Avoid

Avoid contact with incompatible materials.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful

Xn

Risk and Safety Phrases

R22 Harmful if swallowed.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S60 This material and/or its container must be disposed of as hazardous waste.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

S28 After contact with skin, wash immediately with plenty of water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Update of EC Rep Address

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LD50 - Lethal Dose, 50%

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET
HEMOSIL® NORMAL CONTROL 1 UNASSAYED

Doc. ID: SDS00020003120_EN
Revision: 03
CO: 458507
Edited on: 09/25/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® NORMAL CONTROL 1 UNASSAYED**

Product Number: **0020003120**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020003105	**NORMAL CONTROL 1 UNASSAYED**	**Not classified**	**Not classified**	**10 x 1 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **NORMAL CONTROL 1 UNASSAYED**

Product Number: **0020003105**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulation (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	none
Signal word(s):	none
Hazard statement(s):	none
Precautionary statement(s):	none
Other labeling details:	**≈ 100% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: powder containing organic components, human plasma.

3.1 Hazardous components: no known hazardous ingredients.

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion:	If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.
Inhalation exposure:	If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.
Contact with skin:	Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.
Contact with eyes:	Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute:	Inhalation: May cause irritation. Skin: May be irritant for skin. Eyes: May cause irritation. Ingestion: may be harmful.
Delayed:	Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring:	Not foreseen.
Antidotes, if known:	Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray or regular foam, CO_2, dry powder.
Unsuitable extinguishing media:	Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:	Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, SOx, HCl.

5.3 Advice for firefighters

Protective actions:	Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.
Equipment for self-protection:	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed to the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
For emergency responders:	Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3	**Methods and material for containment and cleaning up**	Collect spilled material in containers. Where appropriate, moisten to prevent the dispersion of dust, absorb with inert materials and wash the area with plenty of water. Send to the storage waiting for disposal procedures.
6.4	**Reference to other sections**	See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1	**Precautions for safe handling**	Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.
7.2	**Conditions for safe storage, incompatibilities**	Recommended temperature: store at 2 - 8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.
7.3	**Specific end use**	*Normal Control 1 Unassayed* is intended for in vitro diagnostic use. This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values: Not available

Community/National biological exposure limit values: Not available

DNEL values (components): Not available

PNEC values (components): Not available.

Recommended monitoring procedures:

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you can not prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	Related to
Appearance:	Powder, cake	
Odor:	Odorless	
Color:	Off white	
pH:	Not available	
Flammability:	Not available	
Explosive properties:	Not available	
Oxidizing properties:	Not available	
Density:	Not available	Mixture
Solubility:	Not available	
Water Solubility:	Soluble	Mixture
Melting point/range:	Not available	

9.2 Other information

Miscibility: Miscible

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.3 Possibility of hazardous reactions Not foreseen.

10.4 Conditions to avoid: Keep out from hot temperature, humidity and light.

10.5 Incompatible materials Oxidizing agents.

10.6 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx, HCl.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal: May cause irritation.

Ingestion: Ingestion may cause irritation to the gastrointestinal mucous membranes.

Inhalation: Inhalation of the product may cause irritation to respiratory ways.

Contact with eyes: May cause eye irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion): not available

Acute toxicity	Value	m.u.	Effects	Related to
Oral:	Not available			
Dermal:	Not available			
Inhalation:	Not available			
Other data:	Not available			

Corrosion/Irritation

Skin Corrosion/Irritation	Not available
Serious eye damage/ irritation	Not available

Sensitization:

Skin sensitization:	Not available
Respiratory sensitization:	Not available

CMR effects

Germ cell mutagenicity: Not available

Reproductive toxicity: Not available

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
The components of the mixture are not listed.			

STOT –single exposure Not available.

STOT – repeated exposure Not available

Aspiration hazards Not available.

Other information: Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated.

12.1 Toxicity	**Species, media, units, test duration and test conditions.**	**Related to**
Acute toxicity with fish:	Not available	
Chronic toxicity with fish:	Not available	
Acute toxicity with crustaceans:	Not available	
Chronic toxicity with crustaceans:	Not available	
Acute toxicity with algae:	Not available	
Chronic toxicity with algae:	Not available.	
Toxicity data on soil micro- and macroorganisms:	Not available.	
Toxicity data on birds, bees and plants:	Not available.	

12.2 Persistency and degradability: Not available

12.3 Bioaccumulation potential: Not available

12.4 Mobility in soil: Not expected to adsorb on soil.

12.5 Results of PBT and vPvB assessment Chemical Safety Report and PBT assessment: not performed.

12.6 Other toxic effects: Not available

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	No component listed	
Pennsylvania	No component listed	
		E - Substance is on the Environmental Hazard List

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 07/28/2010.
- Revision n. 01 dated 06/26/2012.
- Revision n. 02 dated 09/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

AIHA: American Industrial Hygiene Association

ADR: Agreement concerning the carriage of dangerous goods by Road

BCF: Bioaccumulative factor

BEI : Biological Esposure Indices

CAS: Chemical Abstract Service (division of the American Chemical Society

CLP: Classification, Labeling and Packaging

DNEL: Derived No-Effect Levels

EC50: The effect concentration associated with 50% response.

EINECS: European Inventory of Existing Commercial Substances

EPA: US Environmental Protection Agency

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association Code

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal Concentration to 50 % of a test population

LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)

LOEL: Lowest Observed Effect Level

MADL: Maximum Allowable Daily (or Dose) Level

NOAEL: No Observed Adverse Effect Level)

NOEC: No observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment

PBT: Persistent, Bio accumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: Very Persistent, very Bio accumulative

WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008: none

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references: none

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
CRITICAL CARE/ HEMOSIL® CLEANING AGENT

Doc. ID: SDS0009832700_EN
Revision: 03
CO: 458649
Edited on: 09/29/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **CRITICAL CARE/HEMOSIL® CLEANING AGENT**

Product Number: **0009832700**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0009832700	**CRITICAL CARE/ HEMOSIL CLEANING AGENT**	**Not classified**	**Not classified**	**1 x 80 mL**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
CRITICAL CARE/ HEMOSIL® CLEANING AGENT

Doc. ID: SDS0009832700_EN
Revision: 03
CO: 458649
Edited on: 09/29/2015

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture:

Product Name: **CRITICAL CARE/HEMOSIL® CLEANING AGENT**

Product Number: **0009832700**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

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526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulation (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	**Safety data sheet available on request.** (EUH210)

Safety precautions:
Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: aqueous solution containing inorganic components.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
Sodium hypochlorite *Index N. (Annex VI of CLP Reg.): 017-011-00-1*	231-668-3	7681-52-9	< 4.9 %	Skin Corrosion/Irritation, cat. 1B Aquatic Acute, cat. 1**	Skin Corr. 1B, H314 Aquatic Acute 1, H400 Specific Conc. Limits EUH031: C ≥ 5 %
Sodium hydroxide *Index N. (Annex VI of CLP Reg.): 011-002-00-6*	215-185-5	1310-73-2	< 0.5 %	Skin Corrosion/Irritation, cat. 1A	Skin Corr. 1A, H314 *Specific Conc. Limits* Skin Corr. 1A,H314: C ≥5% Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture contains substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Sodium hydroxide, Sodium hypochlorite. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation to the mucous membranes and upper respiratory tract.
Skin : May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May cause irritation to the gastrointestinal mucous membranes.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may include toxic and hazardous fumes of Na2O, HCl, Cl2.

5.3 Advice for firefighters

Protective actions:	Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.
Equipment for self-protection:	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
For emergency responders:	Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.
6.2 Environmental precautions	Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
6.3 Methods and material for containment and cleaning up	Soak up with inert absorbent material, and clean with plenty of water. collect spilled material in containers. Send to the storage waiting for disposal procedures.
6.4 Reference to other sections	See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling	Handle in a well ventilated place. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.
7.2 Conditions for safe storage, incompatibilities	Recommended temperature: store at 15-25°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.
7.3 Specific end use	*Critical Care/Hemosil® Cleaning Agent* is intended for in vitro diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

	Limit value – 8 hours	*Limit value – short term*
Sodium hydroxide [(1)(2)]		
Austria	2 mg/m³ - inhalable aerosol	4 mg/m³ - inhalable aerosol
Belgium	2 mg/m³	-
Denmark	2 mg/m³	2 mg/m³
France	2 mg/m³	
Hungary	2 mg/m³	2 mg/m³
New Zealand		2 mg/m³ - ceiling value
Poland	0.5 mg/m³	1 mg/m³
Spain	2 mg/m³	-
Sweden	1 mg/m³	2 mg/m³ - inhalable dust; ceiling value
Switzerland	2 mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol
United Kingdom	-	2 mg/m³
Canada – Québec	-	2 mg/m³ - ceiling value
Canada – Ontario	-	2 mg/m³ - ceiling value

USA – NIOSH	-	2 mg/m³ - ceiling value (15 min)
USA –OSHA	2 mg/m³	-

ACGIH: STEL 2 mg/m³ - ceiling value

NIOSH IDLH: 10 mg/m^3 for NaOH

For ***sodium hypochlorite,*** the occupational exposure limits for **Chlorine** are considered[(1)]:

	Limit value – 8 hours	***Limit value – short term***
Austria	0.5 ppm; 1.5 mg/m³	0.5 ppm; 1.5 mg/m³
Belgium	-	0.5 ppm; 1.5 mg/m³
Denmark	0.5 ppm; 1.5 mg/m³	1.0 ppm; 3.0 mg/m³
European Union	-	0.5 ppm; 1.5 mg/m³
Finland	-	0.5 ppm; 1.5 mg/m³ [(a)]
France	-	0.5 ppm; 1.5 mg/m³ [(b)]
Germany (AGS)	0.5 ppm; 1.5 mg/m³	0.5 ppm; 1.5 mg/m³[(a)]
Germany (DFG)	0.5 ppm; 1.5 mg/m³	0.5 ppm; 1.5 mg/m³
Hungary	-	1.5 mg/m³
Ireland	-	0.5 ppm; 1.5 mg/m³ [(c)]
Italy	-	0.5 ppm; 1.5 mg/m³
Latvia	0.3 ppm; 1 mg/m³	0.5 ppm; 1.5 mg/m³ [(b)]
New Zealand	0.5 ppm; 1.5 mg/m³	1 ppm; 2.9 mg/m³
Poland	0.7 mg/m³	1.5 mg/m³
Spain	-	0.5 ppm; 1.5 mg/m³
Sweden	0.5 ppm; 1.5 mg/m³	1.0 ppm; 3.0 mg/m³ [(d)]
Switzerland	0.5 ppm; 1.5 mg/m³	0.5 ppm; 1.5 mg/m³
The Netherlands	-	1.5 mg/m³
United Kingdom	-	0.5 ppm; 1.5 mg/m³ [(c)]
Canada – Québec	0.5 ppm; 1.5 mg/m³	1 ppm; 2.9 mg/m³
Canada – Ontario	0.5 ppm;	1 ppm;
USA – NIOSH	-	0.5 ppm; 1.42 mg/m³ [(d)]
USA –OSHA	-	1.0 ppm; 3.0 mg/m³

ACGIH 2012[(2)]: TLV – TWA (Chlorine): 0,5 ppm; TLV – STEL (Chlorine): 1 ppm.

[(a)] 15 minutes average value; [(b)] restrictive statutory limit values;
[(c)] 15 minutes reference period; [(d)] ceiling limit value.

Community/National biological exposure limit values: Not established.

DNEL values (components):

Component	*Route of exposure*	*Workers*				*Consumers*			
		Acute effects		*Chronic effects*		*Acute effects*		*Chronic effects*	
		local	*systemic*	*local*	*systemic*	*local*	*systemic*	*local*	*systemic*
Sodium hydroxide *(6)*	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m3)			*1*				1	
Sodium Hypochlorite *(11)*	*Oral (mg/kgbw/day)*								0.26
	Dermal - % in mixture (weight basis)			0.5%				0.5%	
	Inhalation (mg/m3)	3.1	3.1	1.55	1.55	3.1	3.1	1.55	1.55

Sodium hypochlorite [11] : According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for was performed for sodium hypochlorite and the following values were defined:
AEL (Admissible Exposure Level): 0.5 mg/kg bw, derived from NOAL = 50 mg/kg bw, that was established in a study on rats, treated with sodium hypochlorite dissolved in their drinking water for 104 weeks (Hasegawa, 1986), and a safety factor of 100.
ADI (Admissible Daily Intake): 0.5 mg/kg bw, derived from NOAL = 50 mg/kg bw, that was established in a study on rats, treated with sodium hypochlorite dissolved in their drinking water for 104 weeks (Hasegawa, 1986) and a safety factor of 100.

PNEC values (components):

NaOH: Because the buffer capacity, the pH and the fluctuation of the pH are very specific for a certain ecosystem it is not considered useful to derive a PNEC. [4]

Sodium hypochlorite [11] : According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for Sodium hypochlorite was carried out and the following values were defined:

$PNEC_{aquatic}$ = 2.1 µgFAC/L :50 = 0.042 µgFAC/L

$PNEC_{sediments}$ = 0.033 µgFAC/kg, derived from $PNEC_{aquatic}$ using the equilibrium partitioning method in accordance with the technical guideline.

$PNEC_{terrestrial}$ = 0.005 µgFAC/kg derived from $PNEC_{aquatic}$ using the equilibrium partitioning method in accordance with the technical guideline.

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for *Sodium hypochlorite* was carried out and no significant risks were identified in the scenarios of professional uses, described in accordance with the technical guideline for human exposure.[11]
Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	Related to
Appearance:	Clear Liquid	
Odor:	Not available	
Color:	Pale to medium yellow	
pH:	11 - 12	Mixture
Flammability:	Not available	
Explosive properties:	Not available	
Oxidizing properties:	Not available	
Density:	Not available	
Solubility:	Not available	
Water Solubility:	Soluble	
Melting point/range:	Liquid, not applicable	

9.2 Other information

Not available

Partition coefficient octanol/water: *Sodium Hypochlorite*: 0.87 at pH = 7
Sodium Hydroxide: virtually zero [11]

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity:**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability:**	The product is stable until the expiration date shown on the box and on the labels when stored at 15 – 25°C.
10.3	**Possibility of hazardous reactions:**	Not foreseen.
10.4	**Conditions to avoid:**	Keep out from heat and light.
10.5	**Incompatible materials:**	Strong acids, reducing agents, ammonia, ethanol. Contact with acids liberates toxic gas.
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may include toxic and hazardous fumes of Na_2O, HCl, Cl_2.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	May cause skin irritation.
Ingestion:	May cause irritation to the gastrointestinal mucous membranes.
Inhalation:	May cause irritation to the mucous membranes and upper respiratory tract.
Contact with eyes:	May cause serious eye irritation

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Sodium Hypochlorite: The substance is absorbed via oral, dermal and inhalation routes. Pick level in plasma is reached within 2 hours after oral administration to the young animal. The elimination half-life is 44 hours. A study in rats shows that the substance is metabolized to chloride ions, which are distributed in descending order within 96 hours after exposure in plasma, whole blood, bone marrow, testes, kidneys and lungs. Only 51.2% of the dose is excreted 96 hours after exposure, 36.4% in the urine and 14.8% in the feces. After 120 hours, the elimination is not yet completed. [9]

Sodium hydroxide: Alkalis penetrate skin slowly and act at the site of contact. Sodium is a normal constituent of the blood. Exposure to NaOH could potentially increase the pH of the blood. An excess of sodium is avoided through increased elimination which is directed by homeostatic mechanisms. The main excretion route of NaOH is via urine, small amounts were found in faeces, sweat, tears, nasal mucous, saliva, and vaginal and urethral discharges. NaOH is not expected to be systemically available in the body under normal handling and use conditions. [3][4][5]

Acute toxicity	**Value**	**m.u.**	**Effects**	**Related to**
Oral:	LD_0 (rat) > 10.5 g/kg (3.6% solution, as active chlorine); LD_{50} (rat) > 5.8 g/kg (12.5% solution, as active chlorine); LD_{50} (rat) = 8.91 g/kg (commercialized solution of sodium hypochlorite with unspecified concentration).	[11]		Sodium Hypochlorite
Dermal:	LD_{50} > 2000 mg/kg (5.25% solution, as active chlorine)	[11]		Sodium Hypochlorite
Inhalation:	LC_0 > 10.5 mg/l/1 hour (commercial solution with unspecified concentration).	[10]		Sodium Hypochlorite
Other data:	*NaOH:* The existing animal and human data on acute toxicity show that NaOH has a local effect and that systemic effects are not to be expected.[5] *Sodium Hypochlorite:* The toxic effects on the humans depend on the solution concentration. The ingestion of small amounts of common solutions only cause light digestive problems. The concentrated solutions may cause irritation of the digesting tube with vomit, sometimes haemorrhagic. It may cause also necrosis, perforation and complications with shock and haemolysis. The inhalation may cause pulmonary edema. [9] The lowest published toxic dose (oral, woman) = 1000 mg/kg. [10]			

Corrosion/Irritation

Skin Corrosion/Irritation

NaOH is highly irritating and highly corrosive for the skin. (4)

Sodium Hypochlorite: The overall evaluation of data on animal and human skin for concentrations < 5% which are typically marketed for consumer use leads to the conclusion that only mild irritating effects are caused at < 5% sodium hypochlorite. (11) Splashes to the skin of concentrated *Sodium Hypochlorite* may cause severe burns. (9)

Serious eye damage/ irritation

NaOH: even strongly diluted solutions still cause irritation and chemical burns. The available animal data on eye irritation revealed small differences in eye irritation levels. The non-irritant level was 0.2-1.0%, while the corrosive concentration was 1.2% or higher than 2%. There is a danger of blindness. (5)

Sodium Hypochlorite: the contact to eyes of concentrated solutions may cause severe burns with important sequelae.(9) The evaluation of all available data on eye irritation including human exposure leads to the conclusion that in the event of an accidental exposure to concentrations of < 5 % sodium hypochlorite, the risk for pronounced irritant effects is low. (11)

Sensitization:

Skin sensitization:

NaOH is not considered to be a skin sensitizer. (4)

Sodium Hypochlorite did not show any potential for sensitization in three separate guinea pig tests or in standard sensitization patch tests in healthy human volunteers. (11)

Respiratory sensitization:

Not available.

CMR effects

Germ cell mutagenicity;

NaOH: Both the in vitro and the in vivo genetic toxicity test indicate no evidence for a mutagenic activity. (4)

Sodium Hypochlorite: In *in vitro* tests the substance showed mutagenic activity. An increase of chromosome aberration was observed in Chinese hamster cells, but not in human lymphocytes or fibroblasts. Negative results in *in vivo* studies in mouse bone marrow have been reported. (9)(11)

Reproductive toxicity:

NaOH is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the foetus nor reach male and female reproductive organs. (4)

Sodium Hypochlorite: based on limited data from studies on animals, treated with Sodium Hypochlorite in drinking water or from epidemiologic studies on humans, consuming chlorinated drinking water, the substance does not cause effects on fertility or development.(11)

Carcinogenesis:

Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
The components of the mixture are not listed.			

NaOH: Following chemical burns due to alkalis, the incidence of the occurrence of esophageal tumors is increased by a factor between 1000 and 3000. However, the tumor formation is a consequence of massive tissue destruction and the regenerative processes which subsequently start and is not the result of a direct carcinogenic effect. If irritation is avoided, the formation of tumors is not to be expected. (5)

Sodium Hypochlorite: In long term carcinogenicity studies, sodium hypochlorite administered in the drinking water to mice and rats did not show an increase of the tumors incidence. Sodium hypochlorite applied to the skin did not produce skin tumors in mice. In a multigenerational study (6 generations) in rats, sodium hypochlorite administered in the drinking water din not increase the incidence of tumours.(11) The International Agency for Research on Cancer (IARC) has placed the substance in Group 3 (not classifiable as carcinogenic to humans), based on lacking of data in humans and insufficient evidences in animals.(9)

STOT –single exposure

NaOH in the atmosphere causes irritation to the airways (in particular in the nose and throat). A concentration of 2 mg/m3 was reported to have produced distinct but not excessive irritation.

Sodium Hypochlorite: Sodium hypochlorite aerosols may be irritating to the respiratory tract. It is anticipated that exposure to domestic aerosols formulated with sodium hypochlorite solutions of less than 3.0% would not present a significant respiratory irritation hazard.(11)

STOT – repeated exposure

NaOH: In studies in workplaces, irritation to the eyes, nose and throat as well as skin was reported. Animal experimental results also indicate possible chronic damage to the airways. (5)

Sodium Hypochlorite: prolonged use of the substance may cause dermatosis. [9] In studies on animals treated with NaOCl via oral route, a decrease of body weight was observed, but no systemic effects to specific target organs were reported; NOAEL for rats: about 14 mg/kg bw/day (on the basis of chlorine content). No systemic effects were seen following dermal exposure to 10000 mg/l sodium hypochlorite; a NOEL = 1% was chosen for dermal exposure. For the evaluation of the effects of repeated inhalation exposure to hypochlorite aerosols, it is proposed to use data from chlorine. The NOAEL for repeated exposure to chlorine gas is 0.5 ppm, as confirmed by studies in rhesus monkeys and human volunteers. [11][12]

Aspiration hazards The aspiration hazard is not expected, taking into account the use of the mixture.

Other information: Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity	species, media, units, test duration and test conditions.		Related to
Acute toxicity with fish:	LC50 *Gambusia affinis* = 125 mg/l/96 hours	[4]	NaOH
	Based on the weight of evidence, invertebrates show similar sensitivity or greater than fishes in acute ecotoxicity tests with sodium hypochlorite.	[13]	Sodium Hypochlorite
Chronic toxicity with fish:	Upon prolonged exposure concentrations of 25-100 mg/l produced significant changes in the biology of the fish.	[4]	NaOH
Acute toxicity with crustaceans:	LC50 *Ceriodaphnia cf dubia* = 40 mg/l/48 hours. The toxicity threshold concentration for Daphnia magna was reported to range from 40 to 240 mg/l.	[4]	NaOH
	EC50 *Daphnia magna* > 1 mg/l; tested on a mixture containing sodium hypochlorite (immobilization test of Daphnia, in accordance with OECD 202)	[13]	Sodium Hypochlorite 5% solution
Chronic toxicity with crustaceans:	Not available		
Acute toxicity with algae:	Standard tests for acute toxicity for algae are not considered technically feasible for sodium hypochlorite.	[13]	Sodium Hypochlorite
Chronic toxicity with algae:	Not available		
Toxicity data on soil micro- and macroorganisms:	EC50 Photobacterium phosphoreum = 22 mg/l/15 minutes	[4]	NaOH
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability:

NaOH : It is highly soluble in water and dissociates to sodium and hydroxide ions, with the effect of increasing pH and alkalinity. Na+ and OH- persist indefinitely in the environment with equilibrium between various forms of complexes and precipitates. [7]

Sodium Hypochlorite: [14]

The **persistence in atmospheric compartment** is considered as negligible. At environmental pH (6.5 - 8.5), sodium hypochlorite is dissociated into hypochlorous acid and hypochlorite anion (50:50). Only the fraction of hypochlorous acid is volatile. The Henry's Law constant, measured for hypochlorous acid, is 0.0097 Pa m3 mol-1; this suggests that the concentration in air is very low. Therefore the atmospheric compartment is not considered as a significant exposure route.

The **persistence in soil** is considered as very low (Koc, calculated by QSAR = 0.57).

The **persistence in aquatic compartment** is evaluated as poor, in view of the rapid degradation of the substance. Hypochlorite degrades very rapidly (about 300 seconds) in the presence of organic matrixes. [14]

Photo-oxidation, photolysis: Sodium hypochlorite is sensitive to light; sunlight decreases the half-life of a solution containing 10-15% of free chlorine by 3-4 times.

Degradability: ready degradability in fresh water and sea water: not applicable; sodium hypochlorite is an inorganic substance. Degradability of metabolites: not significant; sodium hypochlorite is degraded into chlorine.

12.3 Bioaccumulation potential: Considering its high water solubility, *NaOH* is not expected to bio concentrate in organisms.

12.4 Mobility in soil: *NaOH* is very soluble and mobile in water. In soil, mobility depends directly on the importance of the liquid phase of the soil and the possibility to form metal hydroxo-complexes with metal solid species.(3)

12.5 Results of PBT and vPvB assessment Chemical Safety Report and PBT assessment: not performed.
On the basis of the information available in the literature about Sodium Hypochlorite, the substance does not fulfil PBT and vPvB criteria. It is not persistent and not bio accumulative. (15)

12.6 Other toxic effects: The effect of *NaOH* on the organisms depends on the buffer capacity of the aquatic or terrestrial ecosystem. (4)

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Sodium hydroxide	-
	Sodium hypochlorite	-
New York	Sodium hydroxide	-
	Sodium hypochlorite	-
New Jersey	Sodium hydroxide	Corrosive
	Sodium hypochlorite	Corrosive
Pennsylvania	Sodium hydroxide	E - Substance is on the Environmental Hazard List
	Sodium hypochlorite	E - Substance is on the Environmental Hazard List

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Sodium Hydroxide	1310-73-2	-	-	1,000	-	-	-
Sodium hypochlorite	7681-52-9	-	-	100	-	-	-

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.
According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for *Sodium hypochlorite* was carried out and no significant risks were identified in the scenarios of professional uses, described in accordance with the technical guideline for human exposure.(11)

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 04/15/2011.
- Revision n. 01, dated 07/18/2012.
- Revision n. 02, dated 09/09/2015.
- Revision n. 03, dated 09/29/2015. Main changes are in sections 15.1 and 16, updating information per the most recent version of REACh.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: very Persistent, very Bio accumulative

WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s): H319: Causes serious eye irritation.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H400: Very toxic to aquatic life.

EUH031: Contact with acids liberates toxic gas.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx

(2) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012

(3) IUCLID data set for Sodium hydroxide, 18-feb-2000.

(4) Sodium hydroxide, SIDS Initial Assessment Report For SIAM 14 Paris, 26-28 March 2002

(5) Sodium hydroxide, IFA, GESTIS Substance database , ZVG n. 1270

(6) Sodium hydroxide, ECHA, Registration dossier, available at http://echa.europa.eu/it/information-on-chemicals/registered-substances?p_p_id=registeredsubstances_WAR_regsubsportlet&_registeredsubstances_WAR_regsubsportlet_name-sc=&_registeredsubstances_WAR_regsubsportlet_ec-number-sc=1310-73-2&_registeredsubstances_WAR_regsubsportlet_cas-number-sc=1310-73-2&_registeredsubstances_WAR_regsubsportlet_sc=true&_registeredsubstances_WAR_regsubsportlet_do-search=

(7) Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, available at http://eng.mst.dk/

(8) www.osha.gov, Safety and Health Topics: Sodium Hydroxide

(9) http://modellisds.iss.it/bitstream/123456789/1260/1/127.pdf, Scheda di Dati di Sicurezza secondo l'Allegato II del Regolamento 1907/2006 (REACh), Ipoclorito di sodio, soluzione...%

(10) NIOSH The Registry of Toxic Effects of Chemical Substances, RTECS:NH3486300, Hypochlorous acid, sodium salt

(11) European Union Risk Assessment Report, SODIUM HYPOCHLORITE, Final report, November 2007

(12) GESTIS Substance database, Sodium hypochlorite, solution ... percent Cl active, ZVG No: 1410

(13) A.I.S.E, Environmental classification of sodium hypochlorite containing bleach products.

(14) Evaluation Report on Sodium Hypochlorite (CAS 7681-52-9) for inclusion of the Active Substance in Annex I to Directive 98/8/EC – Bozza Marzo 2010

(15) Eurochlor registration group, Sodium Hypochloride, Final Assessment 2007

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® LOW ABNORMAL CONTROL 2 UNASSAYED

Doc. ID: SDS00020003220_EN
Revision: 02
CO: 458507
Edited on: 09/25/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® LOW ABNORMAL CONTROL 2 UNASSAYED**

Product Number: **0020003220**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020003205	**LOW ABNORMAL CONTROL 2 UNASSAYED**	**Not classified**	**Not classified**	**10 x 1 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **LOW ABNORMAL CONTROL 2 UNASSAYED**

Product Number: **0020003205**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulation (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	**Up to 100% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

Safety precautions:
Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.
Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: powder containing organic and inorganic compounds, human and animal source material.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
2-pyridinethiol-1-oxide sodium salt (sodium pyrithione; sodium omadine)	223-296-5	3811-73-2	< 0.0001 %	Acute Toxicity – Oral, cat. 4 Acute Toxicity – Dermal, cat. 4 Acute Toxicity – Inhalation, cat. 4 Skin Corrosion/Irritation, cat.2 Eye damage/Eye Irritation, cat.2A Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox. 4, H302 Acute Tox. 4, H312 Acute Tox. 4, H332 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Acute 1, H400 (M =100) Aquatic Chronic 1, H410 (M= 10)

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation.
Skin: May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May be harmful.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, SOx.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 2-8°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *Low Abnormal Control 2 Unassayed* is intended for in vitro diagnostic use. The product contains bovine material and human source material. The human source material tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled. This product, as with all human or animal based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

Sodium pyrithion(1)	***Limit value – 8 hours***	***Limit value – short term***
Austria	1 mg/m³	4 mg/m³
Denmark	1 mg/m³	2 mg/m³
Germany (AGS)	1 mg/m³- inhalable aerosol	2 mg/m³ - 15 minutes average value

Germany (DFG)	1mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol
Switzerland	1mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol

Community/National biological exposure limit values: Not established.

DNEL values (components): Not established.

PNEC values (components): Not established.

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Powder, cake	
Odor:	Odorless	
Color:	Off white	
pH:	Neutral	Mixture
Flammability:	Not available	
Explosive properties:	Not available	
Oxidizing properties:	Not available	
Density:	Not available	
Solubility:	Not available	
Water Solubility:	Soluble	
Melting point/range:	Not available	

9.2 Other information Not available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity	This mixture is considered not reactive under the normal conditions of the usage.
10.2 Chemical stability	The product is stable until the expiration date shown on the box and on the labels when stored at 2 –8°C.
10.3 Possibility of hazardous reactions	Not foreseen.
10.4 Conditions to avoid:	Keep out from heat, water, humidity and light.
10.5 Incompatible materials	Oxidizing agents, reducing agents.
10.6 Hazardous decomposition products:	Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	Prolonged or repeated skin contact may cause irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Contact with eyes:	May cause irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

*Sodium pyrithione (*2-pyridinethiol-1-oxide sodium salt) is readily absorbed from the gastrointestinal tract and through the skin. In rats was rapidly absorbed, metabolized, and excreted at all dosing levels. There was no evidence of bioaccumulation of Sodium omadine or its metabolites in the tissues. The urine is the major route of excretion of Sodium omadine (73-85% of the dose); the feces are only a minor route of excretion (5-12% of the dose). Sodium omadine and its metabolites were not excreted in expired air. The major metabolite in rat urine was 2-pyridinethiol-1-oxide-S-glucuronide. [2]

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) =1,500	mg/Kg		[2]	Sodium omadine 40%
	LD50 (rat) =750	mg/Kg		[3]	sodium pyrithione
Dermal:	LD50 (rat) = 1,800	mg/Kg		[2]	Sodium omadine 40%
	LD50 (rat) = 700	mg/Kg		[3]	sodium pyrithione.
Inhalation:	LC50 (rat) = 1.08	mg/l/4h		[2]	Sodium omadine 40%
	LC50 (rat) = 1.1	mg/l/4h		[3]	sodium pyrithione.
Other data:	not available				

Corrosion/Irritation

Skin Corrosion/Irritation	*Sodium pyrithione:* A single dose applied occlusively for 4 hours to the skin of rabbits as a 40% aqueous solution caused mild edema and erythema which had regressed after 72 hours. [4]
Serious eye damage/ irritation	*Sodium pyrithione:* Instillation of a 40 % solution (0.1 ml) into the eyes of rabbits caused mild, transient clouding of the cornea in 2/6 animals 24 hours after application. In all animals mild reddening of the conjunctiva developed and in 2/6 animals had not regressed after 72 hours. Conjunctival reddening was also observed after application of the substance in powder form (10 mg). [4]

Sensitization:

Skin sensitization:	*Bovine serum albumin (BSA),* which is present in bovine plasma, could develop allergic skin reactions in laboratory workers after dealing with BSA powder. Based on the available data, the criteria for classification are not satisfied. *Sodium pyrithione* was not found to be a dermal sensitizer in the tests conducted. [2]
Respiratory sensitization:	*Bovine serum albumin (BSA),* which is present in bovine plasma, could develop allergic reactions in laboratory workers after dealing with BSA powder. It is reported a case of occupational asthma and rhinitis in a laboratory worker caused by the inhalation of 100% BSA powder. The patient had a high serum-spercific IgE level to BSA, and experienced severe systemic reactions, including eye itching, conjunctivitis, rhinorrhea, nasal obstruction, sneezing, shortness of breath, bronchospasm and decreased blood pressure. It was suggested an IgE-mediated response as the pathogenic mechanism. [6] Based on the available data, the criteria for classification are not satisfied.

CMR effects

Germ cell mutagenicity;	*Sodium pyrithione:* Genotoxic effects of the substance could not be demonstrated in the Salmonella mutagenicity test, in the HPRT (hypoxanthine guanine phosphoribosyl transferase) test or in the test for DNA repair in rat hepatocytes. However, because the substance is cytotoxic, only low concentrations could be tested. Negative results were also obtained in vivo in the micronucleus test. [4]
Reproductive toxicity:	*Sodium pyrithione:* Reproductive toxicity is not observed, either after dermal application to rats or rabbits or after oral administration to rats. Embryotoxicity develops in rats but not in rabbits after maternally toxic doses of sodium pyrithione. [4]

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

Sodium pyrithione is not carcinogenic either after dermal application to mice or after oral administration to rats. (4)

STOT –single exposure There are no reports of toxic effects of single exposures of persons to *sodium pyrithione*. (4)

STOT – repeated exposure *Sodium pyrithione:* No signs of toxic effects were observed in nine male workers who had been employed for between 2 and 13 years in the production of sodium pyrithione. In the 90 day dermal toxicity study, rats were given daily doses of Sodium omadine at levels of 0, 5, 15 or 50 mg/kg/day. There was no evidence of dose-related dermal irritation. The NOEL was 15 mg/kg/day in males and 5 mg/kg/day in females.(2) Sodium omadine (41.41% and 40.5% purity) in 40% aqueous solution was administered in water by gavage to groups of 5 male and 5 female Cynomolgus monkeys for 1 year at dose levels of 0, 5, 25, or 150 mg/kg/day. No evidence of toxicity was seen at the 5 mg/kg/day dose other than emesis in some monkeys. The NOAEL was 5 mg/kg/day.(2)

Aspiration hazards Not available.

Other information: *Sodium pyrithione:* Although no signs of neurotoxic effects were seen in monkeys even after intubation of relatively high doses for a period of 1 year, the possibility remains that such effects could develop in man after high level exposures. (4)

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

	Toxicity	**species, media, units, test duration and test conditions.**		**Related to**
	Acute toxicity with fish:	LC_{50} *Lepomis macrochirus* = 6.6-8 µg/l/96 hours	(3)	sodium omadine
	Chronic toxicity with fish:	Not available		
	Acute toxicity with crustaceans:	EC50 water flea Daphnia = 0.022 mg/l/48hours	(5)	sodium omadine
	Chronic toxicity with crustaceans:	Not available		
	Acute toxicity with algae:	ErC50 = 0.46 mg/l/72 hours	(5)	sodium omadine 40.2%
	Chronic toxicity with algae:	NOErC =0.08 mg/L/72 h	(5)	sodium omadine 40.2%
	Toxicity data on soil micro- and macroorganisms	EC50 = 120 mg/L/3 h	(5)	sodium omadine 41%
	Toxicity data on birds, bees and plants:	Mallard duck 8 day dietary LC50 = 10033 ppm Bobwhite quail 8 day dietary LC50 = 3075 ppm	(3)	sodium omadine 40%
		Mallard duck acute oral LD50 = 92 mg/kg Bobwhite quail acute oral LD50 = 200 mg/kg	(3)	sodium omadine 94.9%
12.2	**Persistency and degradability:**	Sodium pyrithione (40.8% sol.) is readily biodegradable. (5)		
12.3	**Bioaccumulation potential:**	Not available.		
12.4	**Mobility in soil:**	Not available.		
12.5	**Results of PBT and vPvB assessment**	Not available.		
12.6	**Other toxic effects:**	Not available.		

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	No component listed	
Pennsylvania	No component listed	

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] [I] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] [I] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] [I] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 12/03/2010.
- Revision n. 01, dated 06/28/2012.
- Revision n. 02, dated 09/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: The effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: No observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: Nery Persistent, very Bio accumulative
WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s):

H302: Harmful if swallowed
H312: Harmful in contact with skin.
H332: Harmful if inhaled.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx

(2) UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Office of Prevention, Pesticides And Toxic Substances, Registration Eligibility Decision(RED) Sodium Omadine, EPA 738-R-95-031, January 1996

(3) Sodium omadine® 40% aq. Sol. Industrial fungicide/bactericide, SDS of the supplier up the supply chain

(4) The MAK Collection for Occupational Health and Safety, Volume 10, Sodium pyrithione, The MAK Collection for Occupational Health and Safety Published Online: 31 JAN 2012

(5) Sodium pyrithione, Registration Dossier, ECHA, http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea00f77-8e69-65ae-e044-00144f67d031/DISS-9ea00f77-8e69-65ae-e044-00144f67d031_DISS-9ea00f77-8e69-65ae-e044-00144f67d031.html

(6) http://e-aair.org - Allergy, Asthma and Immunology Research (AAIR) 2009, October, Occupational asthma caused by inhalation of bovine serum albumin powder, Case report

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® RECOMBIPLASTIN 2G

Doc. ID: SDS00020002950_EN
Revision: 04
CO: 458507
Edited on: 09/25/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® RECOMBIPLASTIN 2G**

Product Number: **0020002950**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020002951	**RTF 2G**	**Not classified**	**Not classified**	**5 x 8 ml**
0020002952	**RTF 2G Diluent**	**Not classified**	**Not classified**	**5 x 8 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **RTF 2G**

Product Number: **0020002951**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	**Safety data sheet available on request.** (EUH210)
	Up to 4.9 % of the mixture consists of component of unknown acute toxicity (dermal, inhalation) for the human health.

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

Warning:
The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.
Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: lyophilised powder containing inorganic and organic compounds and animal source material.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
Tris-Hydroxymethyl aminomethane (Tris Amino)	201-064-4	77-86-1	< 2%	Skin Corrosion/Irritation, cat.2	Skin Irrit. 2, H315
Sodium azide *Index N. (Annex VI of CLP Reg.): 011-004-00-7*	247-852-1	26628-22-8	< 0.2 %	Acute Toxicity – Oral, cat. 2 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)
For exposure limits see ch. 8, for hazard statements text see ch. 16. **** a range may be indicated, considering batch-to batch variation.*** *****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***					

The mixture contains one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Sodium azide. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation.
Skin : May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May be harmful.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, POx, SOx, HBr, HCl.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up Soak up with inert absorbent material, and clean with plenty of water. collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 2-8°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

7.3 Specific end use *RTF 2G* is intended for in vitro diagnostic use. The material contains bovine material, and should be treated as potentially infectious. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled. This product should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

	Limit value – 8 hours	*Limit value – short term*
Sodium azide [(1)(2)]		
European Union [(12)]	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
Austria	0,1 mg/m³	0,3 mg/m³
Belgium	0,1 mg/m³	0,3 mg/m³
Denmark	0,1 mg/m³	0,2 mg/m³
France	0,1 mg/m³ - Restrictive statutory limit value	0,3 mg/m³ - Restrictive statutory limit value
Germany (AGS)	0,2 mg/m³	0,4 mg/m³

Germany (DFG)	0,2 mg/m³ - inhalable aerosol	0,4 mg/m³ - inhalable aerosol
Hungary	0,1 mg/m³	0,3 mg/m³
Italy	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
New Zealand		0,29 mg/m³; 0,11 ppm - ceiling limit value
Poland	0,1 mg/m³	0,3 mg/m³
Spain	0,1 mg/m³	0,3 mg/m³
Switzerland	0,2 mg/m³ - inhalable aerosol	0,4 mg/m³ - inhalable aerosol
United Kingdom	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
The Netherlands	0,1 mg/m³	0,3 mg/m³
Canada – Québec	-	0,3 mg/m³; 0.11 ppm – ceiling value
Canada – Ontario	- -	0.29 ppm – ceiling limit value 0.11 ppm – ceiling limit value as HN_3
USA – NIOSH	-	0.1 ppm – ceiling limit value (as HN3) 0,3 mg/m³ – ceiling limit value (as NaN3)
ACGIH	-	0.29 mg/m³ –ceiling (as Sodium azide) 0.11 ppm – ceiling (as Hydrazoic acid vapor)

Community/National biological exposure limit values: Not established.

DNEL values (components): Not established.

PNEC values (components): Not established.

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Lyophilized powder	
Odor:	Odorless	
Color:	Off White	
pH:	7.3 - 7.5	Mixture
Flammability:	Not available	
Explosive properties:	Not available	

Oxidizing properties:	Not available
Density:	Not available
Solubility:	Not available
Water Solubility:	Soluble
Melting point/range:	Not available

9.2 Other information

Miscibility: Miscible Mixture

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8°C.

10.3 Possibility of hazardous reactions Not foreseen.

10.4 Conditions to avoid: Keep away from heat and light.

10.5 Incompatible materials Strong oxidising agents, acids, alkalis, heavy metals and their salts. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.

10.6 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, POx, SOx, HBr, HCl.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	Prolonged or repeated skin contact may cause irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Contact with eyes:	May cause irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Sodium azide is rapidly absorbed from the respiratory and gastrointestinal tract, and from injection sites. It is also rapidly absorbed by the lungs, and through the skin. The degree of skin penetration via undamaged skin is not clear. The azide anion appeared within 5 min in the plasma of rats following oral administration of 40 mg/kg sodium azide. After 24 h, no more azide could be detected in either plasma or tissue. Sodium azide penetrates the blood-brain barrier and is mainly metabolized in the liver. Its main metabolite in the liver is nitric oxide. Azide anions may be metabolized to nitric oxide (NO) also in the CNS. In aqueous solution, it rapidly transforms into hydrazoic acid, which may be responsible for the irritating effects attributed to sodium azide. Following oral administration of 40 mg/kg sodium azide, no sodium azide was detectable in the feces or in exhaled air and only 7.9 µg were excreted in the 24 h urine.[3][4][5]

Tris amino: is not metabolized appreciably and is eliminated by the kidneys. Ionized tromethamine is excreted by kidney, so the effect is that of excretion of hydrogen ions. Elimination of drug from body is entirely by renal excretion. It is not known whether tromethamine is distributed into human milk. [14]

Acute toxicity	Value	m.u.	Effects		Related to
Oral:	LD50 (rat) = 27	mg/kg		[6]	Sodium azide
	LD50 (rat) > 3,000	mg/kg		[15]	Tris Amino
Dermal:	In the study of Potocar et al. (1985), 3 surviving animals were exposed to 500-1000 mg/kg sodium azide for 1 hour and then to half of that dose for three additional hours on their skins. These data do not support the dermal lethal dose (LD) of sodium azide for rabbits of 18-21 mg/kg, based on a Bassendowska and Kowalski (1961) dermal irritation study, where a single rabbit, exposed to 60 mg substance via the skin, died after 6 hours. Non classified in accordance with the opinion of the European scientific committee.			[4]	Sodium azide
	LD50 (rat) > 5,000	mg/kg		[16]	Tris Amino
Inhalation:	LC50 (rat) = 37	mg/m^3		[6]	Sodium azide

Other data: The most commonly reported health effect from azide exposure is hypotension, almost independent of route of exposure. Fatal doses occur with exposures of > or =700 mg (10 mg/kg). Nonlethal doses ranged from 0.3 to 150 mg (0.004 to 2 mg/kg). Onset of hypotension within minutes or in less than an hour is indicative of a pharmacological response and a benign course. Hypotension with late onset (>1 hour) constitutes an ominous sign for death.[7]

Corrosion/Irritation

Skin Corrosion/Irritation: *Sodium azide:* Dermal (semi-occlusive and occlusive) exposure to 0.5 g/patch solid sodium azide for 1 hour did not produce signs of local irritation in rabbits, whereas exposure for 4 hours was corrosive.[4] In an in vitro Skin Irritation Reconstructed Human Epidermis (RhE) Test Method (9 September 2009), sodium azide was nonirritant to skin. [5] Non classified in accordance with the opinion of the European scientific committee.

Tris Amino: Tromethamine was a mild irritant to rabbits at 25% with a pH of 10.8. At 40%, tromethamine was not irritating. Intradermal injections of tromethamine were severely irritating to rabbits at pH 10.4 but were only mildly irritating at pH 7.4. The supporting substance 2-Amino-2-methyl-1-Propanol (AMP) was found to be irritating to rabbits, with burrowing lesions noted when applied to abraded skin sites; there was mild irritation noted when applied to unabraded skin.[15]

Serious eye damage/ irritation: *Sodium azide:* In a Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (September, 2009) was not considered to be an eye irritant. [5]

Tris Amino (100%) was not an ocular irritant when administered to rabbits. [15]

Sensitization:

Skin sensitization: *Sodium azide:* In a Mouse local lymphnode assay (LLNA) (OECD Guideline 429), sodium azide was not a skin sensitizer. [5]

Tris Amino: The supporting chemical AMP is not sensitizing to guinea pig skin. [15]

Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic skin reactions in laboratory workers after dealing with BSA powder. Based on the available data, the criteria for classification are not satisfied.

Respiratory sensitization: *Bovine serum albumin (BSA),* which is present in bovine plasma, could develop allergic reactions in laboratory workers after dealing with BSA powder. It is reported a case of occupational asthma and rhinitis in a laboratory worker caused by the inhalation of 100% BSA powder. The patient had a high serum-specific IgE level to BSA, and experienced severe systemic reactions, including eye itching, conjunctivitis, rhinorrhea, nasal obstruction, sneezing, shortness of breath, bronchospasm and decreased blood pressure. It was suggested an IgE-mediated response as the pathogenic mechanism. [13] Based on the available data, the criteria for classification are not satisfied.

CMR effects

Germ cell mutagenicity; *Sodium azide* : is highly mutagenic in many plant and bacterial species but marginally mutagenic in mammalian cells. Sodium azide was mutagenic in Salmonella typhimurium strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98. Mutagenicity as observed in bacteria is not relevant for mammals, because of the specific metabolism of sodium azide in bacteria. The existing data support the conclusion that azide may be further modified in mammalian cells to an intermediate that is not genotoxic. [4][8] Negative in a Chromosomal aberration test. In a Cytogenetic tests with Chinese hamster ovary cells, Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations. [9] No studies in mammals are available to adequately assess germ cell effects. [6]

Tris Amino: The supporting chemical, AMP, was not mutagenic to bacteria and mammalian cells in vitro, and did not induce micronuclei in mice in vivo.

Reproductive toxicity: *Sodium azide:* : Insufficient data are available for an assessment of the reproductive toxicity.[11]

Tris Amino: In an oral gavage combined reproductive/developmental toxicity screening test in rats no effects on reproductive or developmental parameters were observed at the doses tested; the NOAEL for reproductive and developmental toxicity is 1000 mg/kg-day, the highest dose tested. [15]

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

Sodium azide: Two long-term oral studies in rats provided no convincing evidence of carcinogenicity, although in both cases the suitability of the test doses has been questioned. At concentrations of 5 and 10 mg/kg sodium azide there was no evidence of carcinogenicity in rats during a 2-year study.[10]

Tris Amino: based on the available data, the substance is not carcinogenic. [17]

STOT –single exposure	*Sodium azide* is not an irritant but is rapidly hydrolyzed to hydrazoic acid in the acidic environment of mucous membranes and the tracheobronchial tree. [4] Hydrazoic acid vapor in concentrations of 0.5 ml/m^3 (0.9 mg/m^3) or more caused irritation of the nasal mucosa. Irritation of the conjunctiva has also been described. [11] Non classified in accordance with the opinion of the european scientific committee.
STOT – repeated exposure	*Sodium azide:* Repeated oral administration caused brain and lung damage in rats, but no such effects have apparently been seen in a corresponding mouse study.[10] Non classified in accordance with the opinion of the European scientific committee.
Aspiration hazards	Not available.
Other information:	The occupational neuropsychotoxicology of sodium azide was investigated annually, for three years in 41 sodium azide exposed workers in a chemical production plant, compared to 42 unexposed ones working in the same plant. Exposed workers presented significantly more acute symptoms of exposure than unexposed workers. Symptoms reported included headache, vertigo, nausea, fatigue, cardiac palpitations, irritated or red eyes. The only recurring chronic symptom was trembling of the hands. No psychological or neuropsychological tests differentiated the exposed from the unexposed group. [4]

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1	**Toxicity**	**species, media, units, test duration and test conditions.**		**Related to**
	Acute toxicity with fish:	LC_{50} *Lepomis macrochirus* = 0.7 mg/l/96 hours	(3)	Sodium azide
		LC50 *Leuciscus idus* > 10,000 mg/L/ 96-h	(15)	Tris Amino
	Chronic toxicity with fish:	Not available		
	Acute toxicity with crustaceans:	EC_{50} *Daphnia pulex* = 4.2 mg/l/96 hours	(3)	Sodium azide
		Water fleas (Daphnia magna) were exposed to AMP at unspecified concentrations for 48 hours. LC50 = 193 mg/L/48 h.	(15)	Tris Amino
	Chronic toxicity with crustaceans:	Not available		
	Acute toxicity with algae:	EC50 *Pseudokirchneriella* = 0.35 mg/l/96 hours	(5)	Sodium azide
		EC50 *Selenastrum capricornutum* >100 mg/L/ 96 h	(15)	Tris Amino
	Chronic toxicity with algae:	Not available.		
	Toxicity data on soil micro- and macroorganisms:	Not available.		
	Toxicity data on birds, bees and plants:	In a bioassay comparable to OECD guideline 208 with slight restrictions, 10 ppm sodium azide in the soil significantly reduced germination and growth in plant species tested, whereas the growth was mostly affected at concentrations above 5 ppm, exhibiting a delay in plant germination. After dissipation of sodium azide normal growth proceeded.	(5)	Sodium azide
12.2	**Persistency and degradability:**	*Tris Amino* is not readily biodegradable is expected to have moderate persistence. [15]		
12.3	**Bioaccumulation potential:**	Not available.		
12.4	**Mobility in soil:**	The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures. [7]		
		Tris Amino is expected to have high mobility in soil. [15]		
12.5	**Results of PBT and vPvB assessment**	Not available.		
12.6	**Other toxic effects:**	Not available.		

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Sodium azide	Extraordinarily hazardous
New York	Sodium azide	A – acutely hazardous substances
New Jersey	Sodium azide	-
Pennsylvania	Sodium azide	E - Substance is on the Environmental Hazard List

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Sodium azide	26628-22-8	500	1,000	1,000	313	P105	-

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed**.**

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 03/31/2010.
- Revision n. 01, dated 05/19/2010.
- Revision n. 02, dated 07/08/2010.
- Revision n. 03, dated 06/26/2012
- Revision n. 04, dated 09/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: The effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: No observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: Very Persistent, very Bio accumulative
WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s):

H300: Fatal if swallowed.
H315: Causes skin irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx

(2) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012

(3) HSDB Hazardous Substances Databank, Sodium azide

(4) Recommendation from the Scientific Committee on Occupational Exposure Limits for sodium azide, SCOEL/SUM/51,September 2009

(5) http://apps.echa.europa.eu/registered/data/dossiers, Sodium azide

(6) ChemIDplus Lite, Sodium azide, full record

(7) http://www.ncbi.nlm.nih.gov/pubmed/12851150, Human health effects of sodium azide exposure: a literature review and analysis. Int J Toxicol. 2003 May-Jun;22(3):175-86.

(8) http://www.ncbi.nlm.nih.gov/pubmed/2671718, Sodium azide mutagenesis in mammals: inability of mammalian cells to convert azide to a mutagenic intermediate. Arenaz P1, Hallberg L, Mancillas F, Gutierrez G, Garcia S.

(9) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)

(10) http://www.bibra-information.co.uk/downloads/toxicity-profile-for-sodium-azide-1992/, Toxicity Profile for Sodium azide (1992)

(11) http://onlinelibrary.wiley.com, The MAK Collection for Occupational Health and Safety, Sodium azide

(12) International Chemical Safety Cards, Sodium azide

(13) http://e-aair.org - Allergy, Asthma and Immunology Research (AAIR) 2009, October, Occupational asthma caused by inhalation of bovine serum albumin powder, Case report

(14) HSDB Hazardous Substances Databank, Tromethamine

(15) Screening-Level Hazard Characterization, Sponsored chemical 2-Amino-2-hydroxymethyl-1,3-propanediol (TRIS AMINO) CASRN 77-86-1, U.S. Environmental Protection Agency, Hazard Characterization Document, September, 2014

(16) ECHA, Registration Dossier, Tromethamine, http://apps.echa.europa.eu/registered/data/dossiers/DISS-d7f60455-0965-1602-e044-00144f67d031/AGGR-932e53a4-4218-4161-b380-2c99a562941f_DISS-d7f60455-0965-1602-e044-00144f67d031.html#AGGR-932e53a4-4218-4161-b380-2c99a562941f

(17) TEST PLAN For Tris(hydroxymethy1)aminomethane (77-86-1) Submitted to the U.S. Environmental Protection Agency Under the High Production Volume (HPV) Chemicals Challenge Program The Dow Chemical Company Midland, Michigan, 48674

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **RTF 2G DILUENT**

Product Number: **0020002952**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
Under normal conditions of use, the mixture does not cause adverse effects to environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	**Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.** (EUH208)

Safety precautions:
Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: aqueous solution containing organic and inorganic compounds.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
Calcium chloride dihydrate *Index N. (Annex VI of CLP Reg.): 017-013-00-2*	233-140-8 (as Calcium chloride anhydrous)	10035-04-8 (10043-52-4 as Calcium chloride anhydr.)	< 0.2%	Eye damage/irritation, cat. 2	Eye Irrit.2, H319
Oxydipropanol (Dipropylene glycol)	246-770-3	25265-71-8	≤ 0.07%	Not classified	Not classified
1,2-benzisothiazolin-3-one (BIT) *Index N. (Annex VI of CLP Reg.): 613-088-00-6*	220-120-9	2634-33-5	≤ 0.02%	Acute Toxicity – Oral, cat. 4 Skin Corrosion/Irritation, cat.2 Eye damage/irritation, cat. 1 Sensitization – Skin, cat.1 Aquatic Acute, cat 1** Aquatic Chronic, cat. 3**	Acute Tox. 4 (*), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M = 1) Aquatic Chronic 3, H412 *Specific Conc. Limits* Skin Sens. 1; H317: C ≥ 0,05 %
Sodium hydroxide *Index N. (Annex VI of CLP Reg.): 011-002-00-6*	215-185-5	1310-73-2	< 0.01%	Skin Corrosion/Irritation, cat. 1A	Skin Corr. 1A, H314 *Specific Conc. Limits* Skin Corr. 1A,H314: C ≥5% Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation to respiratory ways.
Skin : May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May cause irritation to the gastrointestinal mucous membranes.
Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, SOx, HBr, HCl.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up Soak up with inert absorbent material, and clean with plenty of water. collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 2-8°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *RTF 2G Diluent* is intended for in vitro diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

Calcium chloride [(1)]
Canada – Ontario: Occupational exposure limit (OEL) for calcium chloride of 5 mg/m^3 has been established by the Ministry of Labor

Sodium hydroxide [(9)(10)]	*Limit value – 8 hours*	*Limit value – short term*
Austria	2 mg/m³ - inhalable aerosol	4 mg/m³ - inhalable aerosol
Belgium	2 mg/m³	-
Denmark	2 mg/m³	2 mg/m³
France	2 mg/m³	
Hungary	2 mg/m³	2 mg/m³
New Zealand		2 mg/m³ - ceiling value

Poland	0.5 mg/m³	1 mg/m³
Spain	2 mg/m³	-
Sweden	1 mg/m³	2 mg/m³ - inhalable dust; ceiling value
Switzerland	2 mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol
United Kingdom	-	2 mg/m³
Canada – Québec	-	2 mg/m³ - ceiling value
Canada – Ontario	-	2 mg/m³ - ceiling value
USA – NIOSH	-	2 mg/m³ - ceiling value (15 min)
USA –OSHA	2 mg/m³	-

ACGIH: STEL 2 mg/m³ - ceiling value

NIOSH IDLH: 10 mg/m^3 for NaOH

Community/National biological exposure limit values: Not established.

DNEL values (components):

Component	*Route of exposure*	*Workers*				*Consumers*			
		Acute effects		*Chronic effects*		*Acute effects*		*Chronic effects*	
		local	*systemic*	*local*	*systemic*	*local*	*systemic*	*local*	*systemic*
Calcium chloride anhydr. (2)	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m^3)	*10*		*5*		*5*		2.5	
Sodium hydroxide (6)	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m3)			*1*				1	

PNEC values (components): *NaOH:* Because the buffer capacity, the pH and the fluctuation of the pH are very specific for a certain ecosystem it is not considered useful to derive a PNEC. (4)

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Liquid	
Odor:	Odorless	
Color:	Clear	
pH:	not available	Mixture

	Flammability:	Aqueous solution, not expected to be flammable	
	Explosive properties:	Aqueous solution, not expected to be explosive	
	Oxidizing properties:	Aqueous solution, not expected to be oxidant	
	Density:	1.002 g/ml	Mixture
	Solubility:	Not available	
	Water Solubility:	miscible	
	Melting point/range:	Liquid, not applicable	
9.2	**Other information**	Not available	

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability**	The product is stable until the expiration date shown on the box and on the labels when stored at 2 –8°C.
10.3	**Possibility of hazardous reactions**	Not foreseen.
10.4	**Conditions to avoid:**	Keep out from heat and light.
10.5	**Incompatible materials**	Oxidizing agents, reducing agents, strong acid agents, strong basic agents
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx, HCl, HBr.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	Prolonged or repeated skin contact may cause irritation. Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways. Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
Contact with eyes:	May cause irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Calcium chloride : is easily dissociated into calcium and chloride ions in water. The absorption, the distribution and the excretion of the ions in animals are regulated separately. Both ions are essential constituents of the body of all animals. (1)

Sodium hydroxide: Alkalis penetrate skin slowly and act at the site of contact. Sodium is a normal constituent of the blood. Exposure to NaOH could potentially increase the pH of the blood. An excess of sodium is avoided through increased elimination which is directed by homeostatic mechanisms. The main excretion route of NaOH is via urine, small amounts were found in feces, sweat, tears, nasal mucous, saliva, and vaginal and urethral discharges. NaOH is not expected to be systemically available in the body under normal handling and use conditions. (3)(4)(5)

1,2-benzisothiazolin-3-one (BIT): in animals is rapidly and completely metabolized. Neither the substance nor its metabolites do not accumulate in the liver and adipose tissue. The major metabolites are o-(methylsulfinyl)-benzamide and o-(methylsulphonyl)-benzamide. Elimination is within 24 hours and almost entirely through the urine.(11)

Acute toxicity	Value	m.u.	Effects		Related to
Oral:	LD50 (rat) = 3,798 - 4,179 LD50 (rabbit)=500 – 1,000	mg/Kg	The acute oral toxicity is attributed to the severe irritating property of the original substance or its high-concentration solutions to the gastrointestinal tract.	(1)	Calcium chloride
	LD50 (rat) = 670-1,200	mg/Kg		(11)	BIT
Dermal:	LD50 (rabbit) > 5,000	mg/Kg		(1)	Calcium chloride
	LD50 (rabbit) > 2,000	mg/Kg		(11)	BIT
Inhalation:	LC50 (rat) > 40	mg/m^3/4h		(1)	Calcium chloride

Other data: *NaOH:* The existing animal and human data on acute toxicity show that NaOH has a local effect and that systemic effects are not to be expected.(5)

Corrosion/Irritation

Skin Corrosion/Irritation: *Calcium chloride* is not irritating for the skin. (1)

NaOH is highly irritating and highly corrosive for the skin. (4)

1,2-benzisothiazolin-3-one : According to a study conducted in rabbits BIT can be classified as a moderate irritant to skin.(12)

Serious eye damage/ irritation: *Calcium chloride* is irritating for the eyes. (1)

NaOH: even strongly diluted solutions still cause irritation and chemical burns. The available animal data on eye irritation revealed small differences in eye irritation levels. The non-irritant level was 0.2-1.0%, while the corrosive concentration was 1.2% or higher than 2%. There is a danger of blindness. (5)

1,2-benzisothiazolin-3-one : A study in rabbits classified the compound as a severe eye irritant. (12)

Sensitization:

Skin sensitization: *Calcium chloride:* Due to lack of data the classification is not possible.

NaOH is not considered to be a skin sensitizer. (4)

1,2-benzisothiazolin-3-one : A guinea pig maximization test classified BIT as a moderate contact sensitizer whilst the Buehler test classifies BIT as non-sensitizing. Literature data for the local lymph node assay support a classification of BIT as a moderate dermal sensitizer (EC3 2.3%). (In the context of occupational uses, benzisothiazolinone (BIT) is a well-documented contact allergen. (12)

Respiratory sensitization: Not available.

CMR effects

Germ cell mutagenicity; *Calcium chloride:* Genetic toxicity of calcium chloride was negative in the bacterial mutation tests and the mammalian chromosome aberration test. (1)

NaOH: Both the in vitro and the in vivo genetic toxicity test indicate no evidence for a mutagenic activity. (4)

1,2-benzisothiazolin-3-one : The compound has been found to be clastogenic in mammalian cells treated *in vitro,* non-mutagenic *in vitro*, non clastogenic and DNA damaging *in vivo.* (12)

Reproductive toxicity: *NaOH* is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the fetus nor reach male and female reproductive organs. (4)

1,2-benzisothiazolin-3-one : Studies on rats carried out to date did not indicate a reproductive toxic potential (fetal toxicity and teratogenicity) in the maternal-toxic dosage range. (11)

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

NaOH: Following chemical burns due to alkalis, the incidence of the occurrence of esophageal tumors is increased by a factor between 1000 and 3000. However, the tumor formation is a consequence of massive tissue destruction and the regenerative processes which subsequently start and is not the result of a direct carcinogenic effect. If irritation is avoided, the formation of tumors is not to be expected. (5)

1,2-benzisothiazolin-3-one : Based on its characteristics, BIT is unlikely to demonstrate a carcinogenic potential. (13)

STOT –single exposure *NaOH* in the atmosphere causes irritation to the airways (in particular in the nose and throat). A concentration of 2 mg/m3 was reported to have produced distinct but not excessive irritation.

1,2-benzisothiazolin-3-one : At room temperature, exposure to vapor is minimal due to low volatility. A single exposure is unlikely to be hazardous. Mist may cause severe irritation to the upper respiratory tract (nose and throat) and lungs. (13)

STOT – repeated exposure *Calcium chloride:* A study for repeated dose oral toxicity in rats shows no adverse effect of calcium chloride on rats fed 20 mg CaCl2/g diet (comparable to 1000 mg/kg bw/day or more) for 12 months.(1)

NaOH: In studies in workplaces, irritation to the eyes, nose and throat as well as skin was reported. Animal experimental results also indicate possible chronic damage to the airways. (5)

1,2-benzisothiazolin-3-one : A 90-day study on dogs that were administered gelatin capsules with different BIT levels (corresponding to 5; 20 or 50 mg of B per kg of body weight per day) revealed irritations in the gastrointestinal tract (vomiting, diarrhea), slight functional changes of the liver and slightly increased liver weights, but no pathological organ changes. The LOAEL was stated to be 50, and the NOAEL 5, mg per kg of body weight per day. (11)

Aspiration hazards Not available.

Other information: Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity	species, media, units, test duration and test conditions.		Related to
Acute toxicity with fish:	LC50 *Pimephales promelas*= 4,630 mg/l/96 hours	(1)	Calcium chloride
	LC50 *Gambusia affinis* = 125 mg/l/96 hours	(4)	NaOH
	LC50 Oncorhynchus mykiss = 1.9 mg a.i./L/96 h	(14)	1,2-benzisothiazolin-3-one
Chronic toxicity with fish:	Upon prolonged exposure concentrations of 25-100 mg/l produced significant changes in the biology of the fish.	(4)	NaOH
	MATC* (growth) *Pimephales promelas* = 0.41 mg a.i./L/33-day	(14)	1,2-benzisothiazolin-3-one
Acute toxicity with crustaceans:	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(1)	Calcium chloride
	EC50 Daphnia = 3.7 mg a.i./L/48h	(14)	1,2-benzisothiazolin-3-one
	LC50 *Ceriodaphnia cf dubia* = 40 mg/l/48 hours. The toxicity threshold concentration for Daphnia magna was reported to range from 40 to 240 mg/l.	(4)	NaOH
Chronic toxicity with crustaceans:	The chronic toxicity study with Daphnia magna shows that a 16% impairment of reproduction (EC16) is caused at the concentration of 320 mg/L.	(1)	Calcium chloride
	EC50 *Daphnia magna* = 3.8 mg a.i./L/ 21-day Flow-Through Life-Cycle	(14)	1,2-benzisothiazolin-3-one
Acute toxicity with algae:	EC50 *Selenastrum capricornutum* = 2900 mg/L/72 hours (biomass)	(1)	Calcium chloride
	EC50 *Pseudokirchneriella subcapitata* = 0.38-0.98 mg a.i./L/96 h	(14)	1,2-benzisothiazolin-3-one
Chronic toxicity with algae:	Not available.		
Toxicity data on soil micro- and macroorganisms	EC50 Photobacterium phosphoreum = 22 mg/l/15 minutes	(4)	NaOH
	LC50 Eisenia foetida = 278 mg a.i./L	(14)	1,2-benzisothiazolin-3-one
Toxicity data on birds, bees and plants:	Six Terrestrial Plant Species: EC50s = 18.4-166 mg a.i./L/21-day	(14)	1,2-benzisothiazolin-3-one

12.2 Persistency and degradability:

NaOH : It is highly soluble in water and dissociates to sodium and hydroxide ions, with the effect of increasing pH and alkalinity. Na+ and OH- persist indefinitely in the environment with equilibrium between various forms of complexes and precipitates. (7)

The methods for determining the biological degradability are not applicable to inorganic substances. Once emitted into the environment, calcium chloride which has a high water solubility, will dissociate into the calcium and the chloride anion. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulphate and carbonate ions.

1,2-benzisothiazolin-3-one: has a low volatility and is slightly soluble in water. Once introduced into the aquatic environment, BIT will have a tendency to remain in water. BIT is considered degradable and will not persist in the environment. Although the product is hydrolytically stable in water, it is susceptible to photodegradation in aquatic environments. (13)

12.3 Bioaccumulation potential: Considering its high water solubility, *NaOH* is not expected to bio concentrate in organisms.

Considering its dissociation properties, *Calcium chloride* per se is not expected to accumulate in living organisms.

1,2-Benzisothiazolin-3-one: based on a Kow value of 20 at 25°C is unlikely to bio accumulate in aquatic organisms. (14)

12.4 Mobility in soil: *NaOH* is very soluble and mobile in water. In soil, mobility depends directly on the importance of the liquid phase of the soil and the possibility to form metal hydroxo-complexes with metal solid species.(3)

1,2-Benzisothiazolin-3-one shows moderate to strong binding to soil sand it is not likely to migrate into the ground and there is low potential for ground water contamination. (14)

The chloride ion is mobile in soil and eventually drains into surface water because it is readily dissolved in water.

12.5 Results of PBT and vPvB assessment Not available.

12.6 Other toxic effects: The effect of *NaOH* on the organisms depends on the buffer capacity of the aquatic or terrestrial ecosystem. (4)

*** Maximum Acceptable Toxicant Concentrations (MATC) – An estimated value that represents the highest "no-effect" concentration of a specific substance within the range including the NOEC and LOEC.**

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Sodium hydroxide	-
New York	Sodium hydroxide	-
New Jersey	Sodium hydroxide	Corrosive
Pennsylvania	Sodium hydroxide	E - Substance is on the Environmental Hazard List
	Propanol, Oxybis	-

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Sodium Hydroxide	1310-73-2	-	-	1,000	-	-	-

[I]**SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] [I]**SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] [I]**SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV]**CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] [I]**SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI]**RCRA Code:** Resource Conservation and Recovery Act Code
[VII]**CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed**.**

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 03/31/2010.
- Revision n. 01, dated 05/19/2010.
- Revision n. 02, dated 07/08/2010.
- Revision n. 03, dated 06/26/2012
- Revision n. 04, dated 09/25/2015. Main changes are in sections 2 to16, adaptating the sds format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: Very Persistent, very Bio accumulative
WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s):
H319: Causes serious eye irritation.
H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H317: May cause an allergic skin reaction.
H400: Very toxic to aquatic life.
H412: Harmful to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015):

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) Calcium Chloride, SIDS Initial Assessment Report For SIAM 15 Boston, USA 22-25th October 2002
(2) Calcium chloride anh., Registration dossier, available at: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9eb43f6f-23a1-5205-e044-00144f67d031/AGGR-dc2ba8fd-c7fc-402e-906e-b6cd0864ad5e_DISS-9eb43f6f-23a1-5205-e044-00144f67d031.html#AGGR-dc2ba8fd-c7fc-402e-906e-b6cd0864ad5e
(3) IUCLID data set for Sodium hydroxide, 18-feb-2000.
(4) Sodium hydroxide, SIDS Initial Assessment Report For SIAM 14 Paris, 26-28 March 2002
(5) Sodium hydroxide, IFA, GESTIS Substance database , ZVG n. 1270
(6) Sodium hydroxide, ECHA, Registration dossier, available at http://echa.europa.eu/it/information-on-chemicals/registered-substances?p_p_id=registeredsubstances_WAR_regsubsportlet&_registeredsubstances_WAR_regsubsportlet_name-sc=&_registeredsubstances_WAR_regsubsportlet_ec-number-sc=1310-73-2&_registeredsubstances_WAR_regsubsportlet_cas-number-sc=1310-73-2&_registeredsubstances_WAR_regsubsportlet_sc=true&_registeredsubstances_WAR_regsubsportlet_do-search=
(7) Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, available at http://eng.mst.dk/
(8) www.osha.gov, Safety and Health Topics: Sodium Hydroxide
(9) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx
(10) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012
(11) Gestis Substance database, 1,2-Benzisothiazol-3(2H)-one, ZVG 35240
(12) SCCS (Scientific Committee on Consumer Safety), Opinion on benzisothiazolinone, 26-27 June 2012
(13) Product Safety Assessment: 1,2-Benzisothiazol-3(2H)-one (BIT) The Dow Chemical Company, Created: December 4, 2012
(14) Environmental Assessment, FCN 001108, July 26, 2011, http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM287533.pdf

MATERIAL SAFETY DATA SHEET
HEMOSIL® SYNTHASIL

Doc. ID: SDS00020006800_EN
Revision: 01
CO: 430285
Edited on: 07/06/2012

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Identification of the product

Product Name: HEMOSIL® SYNTHASIL

Product Number: 0020006800

1.2 Use of the product: Kit for in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0)3700 492 795
+1 215 207 0061 (USA and Canada)

2. COMPOSITION / INFORMATION ON PRODUCT

P/N	Mixture name	Mixture classification According to 67/548/EEC and 1999/45/EEC Directives	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020006810	SYNTHASIL APTT REAGENT	Not classified	Not classified	5 x 10 mL
0020006910	CALCIUM CHLORIDE 0.020M	Not classified	Not classified	5 x 10 mL

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

Prepared by: Chemsafe Srl

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: SYNTHASIL APTT REAGENT

Product Number: 0020006810

1.2 Use of the mixture: For in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:
+44 (0)3700 492 795
+1 215 207 0061 (USA and Canada)

2. HAZARDS IDENTIFICATION

2.1 Mixture classification ***(see also ch. 15)***

Classified: not dangerous according to 67/548/EEC and 1999/45/EEC Directives

Classified: not hazardous according to 1272/2008/EC Regulation

2.2 Potential health and environmental effects

Ingestion: May be harmful if swallowed.

Inhalation exposure: May cause irritation.

Contact with skin: May cause irritation.

Contact with eyes: May cause irritation.

Sensitization: Might cause sensitization by inhalation or skin contact.

Environmental exposure: Might cause adverse effects for the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition : liquid containing organic and inorganic components.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Formaldehyde (*)	200-001-8	50-00-0	< 0.005 %	Carc. Cat. 3, R40 T, R23/24/25 C, R34 R43 Specific Conc. Limits T, R23/24/25: c ≥ 25% Xn, R20/21/22: 5 % ≤ c < 25 % C, R34: c ≥ 25 % Xi, R36/37/38: 5 % ≤ c < 25 % R43: c ≥ 0,2 %	Carc. 2, H351 Acute Tox. 3 (*), H331 Acute Tox. 3 (*), H311 Acute Tox. 3 (*), H301 Skin Corr. 1B, H314 Skin Sens. 1H317 Specific Conc. Limits Skin Corr. 1B, H314: c ≥ 25 % Skin Irrit. 2, H315: 5 %≤ c <25% Eye Irrit. 2, H319: 5 % ≤ c < 25 % STOT SE 3, H335: c ≥ 5 % Skin Sens. 1, H317: c ≥ 0,2 %
1,2-dibromo-2,4-dicyanobutane	252-681-0	35691-65-7	< 0.015%	Xn, R22 Xi, R38; R41; R43 N, R50	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317, Aquatic Acute 1, H400
For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16					

4. FIRST AID MEASURES

Ingestion:	If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
Inhalation exposure:	If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.
Contact with skin:	Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes:	Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing means:	Water spray or regular foam, CO_2, dry powder.
Mean of extinguishing NOT to be used:	Not known.
Known hazards caused by combustion:	Thermal decomposition or combustion may generate toxic and hazardous fumes (COx, NOx, SOx, HCl).
Equipment for self-protection: (fire fighters):	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
Environmental precautions:	Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
Cleaning procedure to recover spilled material:	Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures:	Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.
Work/Hygienic practices:	Wash hands with soap and water after use.

7.2 Storage

Room ventilation:	Well ventilated workplace.
Special precautions: (see also Section 8)	Avoid environmental release.
Recommended temperature:	Store at 2 – 8 °C.
Humidity, light and other environmental factors:	Avoid light exposure and keep away from heat sources and non compatible materials.
Containers:	Keep containers tightly closed and labeled with the name of the product.
Other storage precautions:	Keep away from food and drinks.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

OSHA Permissible Exposure Limit (PEL) for General Industry: 0.75 ppm TWA; 2 ppm STEL, related to Formaldehyde (1)	LV EU: not available
Threshold Limit Value (TLV) (ACGIH): 0.3 ppm, 0.37 mg/m^3 Ceiling, related to Formaldehyde (1)	MAK: 0.3 ppm, 0.37 mg/m^3, related to Formaldehyde (2)
NIOSH Recommended Exposure Limit (REL): 0.016 ppm TWA, 0.1 ppm Ceiling (15 Minutes), related to Formaldehyde (1)	
NIOSH Immediately Dangerous To Life or Health Concentration (IDLH): 20 ppm, related to Formaldehyde (1)	

8.2 Exposure Controls

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.
Skin protection:	Protective clothing, rubber or polythene gloves.
Eye protection:	Safety glasses.
Hand protection:	Rubber or polythene gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.
Environmental protection:	Avoid any release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance:	Liquid
Odor:	Odorless
Color:	Slightly turbid

9.2 Important health, safety and environmental information

	Value	Related to
pH:	7.15 – 7.35	Mixture
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	1.028 g/ml	Mixture
Solubility:	not available	
Water Solubility:	miscible	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	

9.3 Other information

Melting point/range: not available

10. STABILITY AND REACTIVITY

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8 °C.

10.1 Conditions to avoid: Keep out from heat and light.

10.2 Materials to avoid: Oxidizing agents, reducing agents.

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx, HCl.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption: Formaldehyde is rapidly absorbed from the respiratory tract and gastrointestinal and poorly absorbed following dermal application. (2)

1,2-dibromo-2,4-dicyanobutane is readily absorbed following oral and dermal administration. (7)

Distribution: Formaldehyde will partition into richly vascularized organs, haematopoietic organs, gastrointestinal mucosa, exocrine pancreas, salivary glands. (2)

Metabolism: Formaldehyde is metabolized by the enzyme formaldehyde dehydrogenase to formate and then the carbon atom is oxidized to carbon dioxide or incorporated into purines, thymidine and aminoacids. Both formaldehyde and formate does not accumulate in tissues. (2)

Excretion: not available

11.2 Acute toxicity

	Value	m.u.	Effects		Related to
Oral:	LD50 (rat) = 100	mg/Kg		(3)	Formaldehyde
	LD50 (rat) = 515	mg/Kg		(7)	1,2-dibromo-2,4-dicyanobutane
Dermal:	LD50 (rat) = 270	mg/Kg		(3)	Formaldehyde
	LD50 (rabbit) > 5000	mg/Kg		(7)	1,2-dibromo-2,4-dicyanobutane
Inhalation:	LC50 (rat) = 0.578	mg/l/4h		(4)	Formaldehyde
	LC50 (rat) > 13,000	mg/l/4h		(7)	1,2-dibromo-2,4-dicyanobutane

Other data: not available

11.3 Irritation

Skin: Formaldehyde solutions (0.1–20%) were applied to rabbit skin and produced mild to moderate irritations. (4) Solutions of 40% formaldehyde produce caustic injuries. (2)

Equivocal results were obtained from skin irritation tests with 1,2-dibromo-2,4-dicyanobutane in animal studies. (7)

Eye: Formaldehyde may in some individuals be mildly irritating to the eyes in airborne concentrations down to 0.01 ppm. Aqueous solutions of formaldehyde accidentally splashed into the eyes have caused severe injuries. Ocular irritation is observed in animals exposed to formaldehyde vapour at concentrations of 15 ppm. (5)

In pure form (98%), 1,2-dibromo-2,4-dicyanobutane is a severe eye irritant. Instillation of 1,2-dibromo-2,4-dicyanobutane powder into the rabbit eye resulted in severe irritation, which persisted for at least 21 days post-instillation.(7)

Inhalation: Upper airway irritation to Formaldehyde vapour occurs at 0.1-25 ppm. Lower airway irritation is reported at 5-30 ppm. (5)

11.4 Sensitization:

Skin sensitization: Formaldehyde is a relatively strong contact allergen and contact allergy may develop after contact with products, which contain less than 1% formaldehyde. (5)

Results from three local lymph node assays (LLNA) and from two novel adjuvant methods for assessing skin sensitisation potential strongly suggest that 1,2-dibromo-2,4-dicyanobutane is a sensitising agent[7]

Sensitization by inhalation: not available

11.5 Prolonged exposure toxicity: Chronic studies with rats given Formaldehyde in drinking water showed adverse effects in the animals receiving the highest dose (about 100 mg/kg of body weight). The effects were low body weight and pathological changes in the stomach. [5]

Repeated dermal application of 1,2-dibromo-2,4-dicyanobutane was associated with moderate to severe erythema and slight to moderate oedema. Non-neoplastic lesions at the application site such as epidermal hyperplasia, hyperkeratosis, parakeratosis, necrosis, and ulcers were observed. Dermal chronic active inflammation and sebaceous gland hyperplasia were also reported. [7]

11.6 CMR effects

				Related to
Mutagenicity:	Ames test:	Positive in some strains	[6]	Formaldehyde
		Negative		1,2-dibromo-2,4-dicyanobutane
	Mouse lymphoma:	not available		
	Chromosomal aberration:	positive	[8]	1,2-dibromo-2,4-dicyanobutane
	Cytogenetic tests with Chinese hamster ovary cells:	Positive	[6]	Formaldehyde
	Micronucleus test:	Formaldehyde increased the number of micronuclei and nuclear anomalies in epithelial cells in rats by oral administration.	[5]	Formaldehyde

Teratogenesis: No teratogenic effects were seen in mice given Formaldehyde orally, in an aqueous solution containing about 0.2% formaldehyde, on day 6-15 of gestation. The oral doses were 74, 148, 185 mg/kg body weight. No effects on fetus size and no skeletal or visceral abnormalities were observed. [5]

In a study in rats exposed to 1,2-dibromo-2,4-dicyanobutane, a NOAEL for developmental toxicity was determined to be 175 mg/kg bw. Available information suggests that the substance is neither a reproductive nor a developmental toxin at doses that are not associated with maternal toxicity. [7]

Carcinogenesis: The International Agency for Research on Cancer (IARC) has placed Formaldehyde in group 2A (probably carcinogenic to humans). There is limited evidence for the carcinogenicity to humans and sufficient evidence for carcinogenicity in experimental animals.[5]

Under the conditions of these 2-year dermal studies there was no evidence of carcinogenic activity of 1,2-dibromo-2,4- dicyanobutane in male or female rats administered 2, 6, or 18 mg/kg. [8]

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology	Value	m.u.		Related to
Acute toxicity with fish:	LC50 Zebra fish = 41	mg/l/96 hours	[5]	Formaldehyde
Acute toxicity with Daphnia Magna:	EC50 = 6.16	mg/l/48 hours	[9]	1,2-dibromo-2,4-dicyanobutane
Acute toxicity with algae:	ErC50 Green algae = 0.15	mg/l/72 hours	[9]	1,2-dibromo-2,4-dicyanobutane

12.2 Mobility: 1,2-dibromo-2,4-dicyanobutane is expected to be very mobile and nonpersistent in aquatic and soil environments. [10]

12.3 Persistency and degradability: The biodegradability of formaldehyde has been determined according to BOD5 methods by which a degradation of 97.4% and > 60% was determined. [2]

1,2-dibromo-2,4-dicyanobutane is expected to degrade rapidly in aquatic environments. [10]

12.4 Bioaccumulation potential: Bioconcentration potential of Formaldehyde is insignificant.

12.5 Evaluation PBT result: not available

12.6 Other toxic effects: not available

13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.
Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. TRANSPORT INFORMATION

Not classified for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

15. REGULATORY INFORMATION

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

	According to 67/548/EEC and 1999/45/EEC Directives	According to 1272/2008/EC Regulation
Classification:	Not classified as dangerous	Not classified as hazardous
Labeling symbols: (signal word)	none	none
Labeling risk phrases: (hazard statements)	none	none
Labeling safety phrases: (precautionary statements)	none	none

Other labeling details: ≈ 6.5% percent of this mixture consist of ingredient(s) of unknown toxicity for human health and aquatic environment.

Safety precautions: Wear suitable protective clothing, gloves and eye/face protection.

Authorization: no

Restriction: no

16. OTHER INFORMATION

Phrases R:
R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.
R40: Limited evidence of a carcinogenic effect.
R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.
R34: Causes burns.
R43: May cause sensitisation by skin contact.
R36/37/38: Irritating to eyes, respiratory system and skin.
R22: Harmful if swallowed.
R38: Irritating to skin.
R41: Risk of serious damage to eyes.
R50: Very toxic to aquatic organisms.

Hazard Statements:
H351: Suspected of causing cancer
H311: Toxic in contact with skin.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H302: Harmful if swallowed.
H318: Causes serious eye damage.
H400: Very toxic to aquatic life.

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI “Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation” (ANSI Z400.1-2004) as recommended by US OSHA.

Bibliographic references:

(1) United States Dpartment of Labor, Occupational safety & Health Administration, Chemical Sampling Information, Formaldehyde

(2) http://www.salute.gov.it/sicurezzaChimica/paginaInternaMenuSicurezzaChimica, MSDS for Formaldehyde

(3) ChemIdplus Lite, Formaldehyde, Full record

(4) IUCLID dataset for Formaldehyde, date: 18 feb. 2000

(5) Danish Ministry of Enviroment, Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, Formaldehyde

(6) Chemical Carcinogenesis Research Information System (CCRIS), a database of the National Library of Medicine's TOXNET system, Records containing the term Formaldehyde

(7) Australian Government, deaprtment of Health and Ageing, NICNAS Existing Chemiclas Information Sheet, Methyldibromo Glutaronitrile, June 2009

(8) NTP Database, Study Abstract for 1,2-Dibromo-2,4-dicyanobutane

(9) LANXESS, Material Safety Data Sheet for Tektamer 38LV

(10) EPA R.E.D. Facts, DIBROMODICYANOBUTANE

(*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008 Regulation (EC).

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: CALCIUM CHLORIDE 0.020M

Product Number: 0020006910

1.2 Use of the mixture: For in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0)3700 492 795
+1 215 207 0061 (USA and Canada)

2. HAZARDS IDENTIFICATION

2.1 Mixture classification ***(see also ch. 15)***

Classified: not dangerous according to 67/548/EEC and 1999/45/EEC Directives

Classified: not hazardous according to 1272/2008/EC Regulation

2.2 Potential health and environmental effects

Ingestion: May be harmful if swallowed.

Inhalation exposure: May cause irritation.

Contact with skin: May cause irritation.

Contact with eyes: May cause irritation.

Sensitization: Might cause sensitization by inhalation or skin contact.

Environmental exposure: Might cause adverse effects for the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: liquid containing inorganic components.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Sodium Azide (*)	247-852-1	26628-22-8	< 0.03 %	T+; R28, R32 N; R50-53	Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Calcium chloride dihydrate (*)	233-140-8 (as Calcium chloride anhydrous)	10035-04-8 (10043-52-4 as Calcium chloride anhydr.)	< 0.3 %	Xi, R36	Eye irrit. 2, H319
For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16					

4. FIRST AID MEASURES

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

Contact with skin:	Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes:	Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing means:	Water spray or regular foam, CO_2, dry powder.
Mean of extinguishing NOT to be used:	Not known.
Known hazards caused by combustion:	Thermal decomposition or combustion may generate toxic and hazardous fumes (Na_2O, HCl).
Equipment for self-protection: (fire fighters):	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
Environmental precautions:	Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
Cleaning procedure to recover spilled material:	Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures:	Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.
Work/Hygienic practices:	Wash hands with soap and water after use.

7.2 Storage

Room ventilation:	Well ventilated workplace.
Special precautions: (see also Section 8)	Avoid environmental release.
Recommended temperature:	Store at 2 – 8 °C.
Humidity, light and other environmental factors:	Avoid light exposure and keep away from heat sources and non compatible materials.
Containers:	Keep containers tightly closed and labeled with the name of the product.
Other storage precautions:	Keep away from food and drinks. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV/TWA: 0.1 mg/m^3 for Sodium azide [(1)]

TLV /STEL: 0.3 mg/m^3 for Sodium azide [(1)]

TLV-CEILING (ACGIH): 0.29 mg/m^3 for Sodium azide [(1)]

EU OEL: 0.1 mg/m³ as TWA, 0.3 mg/m^3 as STEL (skin) for Sodium azide [(1)]

US OSHA PEL FINAL-CL: 0.3 mg/m^3 (as NaN_3) (skin) for Sodium azide

MAK: 0.2 mg/m^3, inhalable fraction for Sodium azide [(2)]

OES (UK): 10 mg/m^3 related to Calcium chloride [(6)]

8.2 Exposure Controls

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.
Skin protection:	Protective clothing, rubber or polythene gloves.
Eye protection:	Safety glasses.

Hand protection:	Rubber or polythene gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.
Environmental protection:	Avoid any release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance:	Liquid
Odor:	Odorless
Color:	Clear

9.2 Important health, safety and environmental information

	Value	Related to
pH:	not available	
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	1.000 g/ml	Mixture
Solubility:	not available	
Water Solubility:	miscible	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	

9.3 Other information

Melting point/range:	not available

10. STABILITY AND REACTIVITY

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8 °C.

10.1	Conditions to avoid:	Keep away from heat and light.
10.2	Materials to avoid:	Oxidizing agents, reducing agents, strong acid agents, strong basic agents. Keep away from acids (sodium azide reacts strongly) and away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.
10.3	Hazardous decomposition products:	Thermal decomposition or combustion may include toxic and hazardous fumes of Na2O, HCl.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption:	Sodium azide is rapidly absorbed from the gastrointestinal tract and from injection sites. [3]
Distribution:	not available
Metabolism:	not available
Excretion:	not available

11.2 Acute toxicity

	Value	m.u.	Effects		Related to
Oral:	LD50 (rat) = 27	mg/Kg		[4]	Sodium azide
	LD50 (rat) = 1,000 - 4,179	mg/Kg		[6]	Calcium chloride
Dermal:	LD50 (rat) = 50	mg/Kg		[4]	Sodium azide
	LD50 (rat) = 2,630	mg/Kg		[6]	Calcium chloride
Inhalation:	LC50 (rat) = 37	mg/m^3		[4]	Sodium azide

	Other data:	not available
11.3	Irritation	
	Skin:	Calcium chloride is not irritating for the skin. [6]
	Eye:	Calcium chloride is irritating for the eyes. [6]
	Inhalation:	not available
11.4	Sensitization:	
	Skin sensitization:	not available
	Sensitization by inhalation:	not available
11.5	Prolonged exposure toxicity:	not available

11.6 CMR effects

				Related to
Mutagenicity:	Ames test:	Sodium azide was mutagenic in *Salmonella typhimurium* strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98.	[5]	Sodium azide
	Mouse lymphoma:	not available		
	Chromosomal aberration:	Negative	[5]	Sodium azide
	Cytogenetic tests with Chinese hamster ovary cells:	Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations.	[5]	Sodium azide
	Micronucleus test:	not available		

Teratogenesis:	In a teratogenic study employng albino rats treated orally with technical Sodium azide at dose levels of 0.5, 1.5, or 5.0 mg/kg daily during gestation days 6 through 15, no teratogenic effects dur to Sodium azide were found. Sterility has been produced in male mice given sodium azide. [3]
Carcinogenesis:	Carcinogenicity studies were conducted by administering sodium azide (greater than 99% pure) in distilled water by gavage to groups of male and female rats once daily, 5 days per week for 14 days, 13 weeks, or 2 years. Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of sodium azide in male or female rats administered 5 or 10 mg/kg. Sodium azide induced necrosis in the cerebrum and the thalamus of the brain in both male and female rats. [5]

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology

	Value	m.u.		Related to
Acute toxicity with fish:	LC50 bluegill fish = 0.7	mg/l/96 hours	[3]	Sodium azide
	LC50 Gambusia afinis = 10,000	mg/l/96 hours	[6]	Calcium chloride
Acute toxicity with Daphnia Magna:	EC50 daphnia pulex = 4.2	mg/l/96 hours	[3]	Sodium azide
	EC50 Daphnia magna = 144	mg/l/48 hours	[6]	Calcium chloride
Acute toxicity with algae:	ErC50 = not available	mg/l/72 hours		

12.2	Mobility:	The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures. [3]
12.3	Persistency and degradability:	not available
12.4	Bioaccumulation potential:	not available
12.5	Evaluation PBT result:	not available
12.6	Other toxic effects:	not available

13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.
Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. TRANSPORT INFORMATION

Not classified as dangerous for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

15. REGULATORY INFORMATION

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

	According to 67/548/EEC and 1999/45/EEC Directives	According to 1272/2008/EC Regulation
Classification:	Not classified as dangerous	Not classified as hazardous
Labeling symbols: (signal word)	none	none
Labeling risk phrases: (hazard statements)	none	none
Labeling safety phrases: (precautionary statements)	none	none

Other labeling details: no

Safety precautions: Wear suitable protective clothing, gloves and eye/face protection.

Authorization: no

Restriction: no

16. OTHER INFORMATION

Phrases R: R28: Very toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R36: Irritating to eyes.

Hazard Statements: H300: Fatal if swallowed.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

Bibliographic references:

(1) International Chemical Safety Cards, Sodium azide
(2) Haz-Map Occupational exposure to hazardous Agents, Sodium azide
(3) HSDB Hazardous Substances Databank, Sodium azide
(4) ChemIDplus Lite, Sodium azide, full record
(5) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)
(6) IUCLID data set for Calcium Chloride, 18-feb-2000
(*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008/EC Regulation

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® WASH-R-EMULSION

Doc. ID: SDS00020002400_EN
Revision: 03
CO: 458507
Edited on: 09/25/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® WASH-R-EMULSION**

Product Number: **0020002400**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020002400	**WASH-R-EMULSION**	**Not classified**	**Not classified**	**1000 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **WASH-R-EMULSION**

Product Number: **0020002400**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	None

Safety precautions:
Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: aqueous solution containing organic and inorganic components.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
Sodium azide *Index N. (Annex VI of CLP Reg.): 011-004-00-7*	247-852-1	26628-22-8	≤ 0.1 %	Acute Toxicity – Oral, cat. 2 Aquatic Acute 1** Aquatic Chronic 1**	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture contains one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Sodium azide. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation.
Skin: May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May be harmful.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, Na2O.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed to the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 15-25°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

7.3 Specific end use *WASH-R-EMULSION* is intended for in vitro diagnostic use**.** Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

	Limit value – 8 hours	*Limit value – short term*
Sodium azide [(1)(2)]		
European Union [(12)]	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
Austria	0,1 mg/m³	0,3 mg/m³
Belgium	0,1 mg/m³	0,3 mg/m³
Denmark	0,1 mg/m³	0,2 mg/m³
France	0,1 mg/m³ - Restrictive statutory limit value	0,3 mg/m³ - Restrictive statutory limit value
Germany (AGS)	0,2 mg/m³	0,4 mg/m³
Germany (DFG)	0,2 mg/m³ - inhalable aerosol	0,4 mg/m³ - inhalable aerosol
Hungary	0,1 mg/m³	0,3 mg/m³
Italy	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
New Zealand		0,29 mg/m³; 0,11 ppm - ceiling limit value
Poland	0,1 mg/m³	0,3 mg/m³
Spain	0,1 mg/m³	0,3 mg/m³
Switzerland	0,2 mg/m³ - inhalable aerosol	0,4 mg/m³ - inhalable aerosol
United Kingdom	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
The Netherlands	0,1 mg/m³	0,3 mg/m³

Canada – Québec	-	0,3 mg/m³; 0.11 ppm – ceiling value
Canada – Ontario	- -	0.29 ppm – ceiling limit value 0.11 ppm – ceiling limit value as HN_3
USA – NIOSH	-	0.1 ppm – ceiling limit value (as HN3) 0,3 mg/m³ – ceiling limit value (as NaN3)
ACGIH	-	0.29 mg/m³ –ceiling (as Sodium azide) 0.11 ppm – ceiling (as Hydrazoic acid vapor)

Community/National biological exposure limit values: Not established.

DNEL values (components): Not established.

PNEC values (components): Not established.

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Opaque Liquid	
Odor:	Not available	
Color:	White	
pH:	Not available	Mixture
Flammability:	Aqueous solution, not expected to be flammable	
Explosive properties:	Aqueous solution, not expected to be explosive	
Oxidizing properties:	Aqueous solution, not expected to be oxidant	
Density:	Not available	
Solubility:	Not available	
Water Solubility:	Miscible	
Melting point/range:	Liquid, not applicable	

9.2 Other information

Miscibility:	Miscible	Mixture

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability**	The product is stable until the expiration date shown on the box and on the labels when stored at 15 –25 °C.
10.3	**Possibility of hazardous reactions**	Not foreseen.
10.4	**Conditions to avoid:**	Keep away from heat and light.
10.5	**Incompatible materials**	Strong oxidising agents, acids, alkalis, heavy metals and their salts. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, Na2O.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	Prolonged or repeated skin contact may cause irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Contact with eyes:	May cause irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Sodium azide is rapidly absorbed from the respiratory and gastrointestinal tract, and from injection sites. It is also rapidly absorbed by the lungs, and through the skin. The degree of skin penetration via undamaged skin is not clear. The azide anion appeared within 5 min in the plasma of rats following oral administration of 40 mg/kg sodium azide. After 24 h, no more azide could be detected in either plasma or tissue. Sodium azide penetrates the blood-brain barrier and is mainly metabolized in the liver. Its main metabolite in the liver is nitric oxide. Azide anions may be metabolized to nitric oxide (NO) also in the CNS. In aqueous solution, it rapidly transforms into hydrazoic acid, which may be responsible for the irritating effects attributed to sodium azide. Following oral administration of 40 mg/kg sodium azide, no sodium azide was detectable in the feces or in exhaled air and only 7.9 µg were excreted in the 24 h urine.[3][4][5]

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) = 27	mg/kg		[6]	Sodium azide
Dermal:	In the study of Potocar et al. (1985), 3 surviving animals were exposed to 500-1000 mg/kg sodium azide for 1 hour and then to half of that dose for three additional hours on their skins. These data do not support the dermal lethal dose (LD) of sodium azide for rabbits of 18-21 mg/kg, based on a Bassendowska and Kowalski (1961) dermal irritation study, where a single rabbit, exposed to 60 mg substance via the skin, died after 6 hours. Non-classified in accordance with the opinion of the European scientific committee.			[4]	Sodium azide
Inhalation:	LC50 (rat) = 37	mg/m^3		[6]	Sodium azide
Other data:	The most commonly reported health effect from azide exposure is hypotension, almost independent of route of exposure. Fatal doses occur with exposures of > or =700 mg (10 mg/kg). Nonlethal doses ranged from 0.3 to 150 mg (0.004 to 2 mg/kg). Onset of hypotension within minutes or in less than an hour is indicative of a pharmacological response and a benign course. Hypotension with late onset (>1 hour) constitutes an ominous sign for death.[7]				

Corrosion/Irritation

Skin Corrosion/Irritation	*Sodium azide:* Dermal (semi-occlusive and occlusive) exposure to 0.5 g/patch solid sodium azide for 1 hour did not produce signs of local irritation in rabbits, whereas exposure for 4 hours was corrosive.[4] In an in vitro Skin Irritation Reconstructed Human Epidermis (RhE) Test Method (9 September 2009), sodium azide was nonirritant to skin. [5] Non classified in accordance with the opinion of the European scientific committee.
Serious eye damage/ irritation	*Sodium azide:* In a Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (September, 2009) was not considered to be an eye irritant. [5]

Sensitization:

Skin sensitization: *Sodium azide:* In a Mouse local lymph node assay (LLNA) (OECD Guideline 429), sodium azide was not a skin sensitizer. (5)

Respiratory sensitization: Not available.

CMR effects

Germ cell mutagenicity; *Sodium azide* : is highly mutagenic in many plant and bacterial species but marginally mutagenic in mammalian cells. Sodium azide was mutagenic in Salmonella typhimurium strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98. Mutagenicity as observed in bacteria is not relevant for mammals, because of the specific metabolism of sodium azide in bacteria. The existing data support the conclusion that azide may be further modified in mammalian cells to an intermediate that is not genotoxic. (4)(8) Negative in a Chromosomal aberration test. In a Cytogenetic tests with Chinese hamster ovary cells, Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations. (9) No studies in mammals are available to adequately assess germ cell effects. (6)

Reproductive toxicity: *Sodium azide:* : Insufficient data are available for an assessment of the reproductive toxicity.(11)

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

Sodium azide: Two long-term oral studies in rats provided no convincing evidence of carcinogenicity, although in both cases the suitability of the test doses has been questioned. At concentrations of 5 and 10 mg/kg sodium azide there was no evidence of carcinogenicity in rats during a 2-year study.(10)

STOT –single exposure *Sodium azide* is not an irritant but is rapidly hydrolyzed to hydrazoic acid in the acidic environment of mucous membranes and the tracheobronchial tree. (4) Hydrazoic acid vapor in concentrations of 0.5 ml/m^3 (0.9 mg/m^3) or more caused irritation of the nasal mucosa. Irritation of the conjunctiva has also been described. (11) Non classified in accordance with the opinion of the European scientific committee.

STOT – repeated exposure *Sodium azide:* Repeated oral administration caused brain and lung damage in rats, but no such effects have apparently been seen in a corresponding mouse study.(10) Non classified in accordance with the opinion of the European scientific committee.

Aspiration hazards Not available.

Other information: The occupational neuropsychotoxicology of sodium azide was investigated annually, for three years in 41 sodium azide exposed workers in a chemical production plant, compared to 42 unexposed ones working in the same plant. Exposed workers presented significantly more acute symptoms of exposure than unexposed workers. Symptoms reported included headache, vertigo, nausea, fatigue, cardiac palpitations, irritated or red eyes. The only recurring chronic symptom was trembling of the hands. No psychological or neuropsychological tests differentiated the exposed from the unexposed group. (4)

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity	**Species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC_{50} *Lepomis macrochirus* = 0.7 mg/l/96 hours	(3)	Sodium azide
Chronic toxicity with fish:	Not available		
Acute toxicity with crustaceans:	EC_{50} *Daphnia pulex* = 4.2 mg/l/96 hours	(3)	Sodium azide
Chronic toxicity with crustaceans:	Not available		
Acute toxicity with algae:	EC50 *Pseudokirchneriella* = 0.35 mg/l/96 hours	(5)	Sodium azide
Chronic toxicity with algae:	Not available.		
Toxicity data on soil micro- and macroorganisms:	Not available.		

	Toxicity data on birds, bees and plants:	In a bioassay comparable to OECD guideline 208 with slight restrictions, 10 ppm sodium azide in the soil significantly reduced germination and growth in plant species tested, whereas the growth was mostly affected at concentrations above 5 ppm, exhibiting a delay in plant germination. After dissipation of sodium azide normal growth proceeded.	(5)	Sodium azide

12.2 Persistency and degradability: Biodegradability is not applicable.

12.3 Bioaccumulation potential: Not available.

12.4 Mobility in soil: The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures. (7)

12.5 Results of PBT and vPvB assessment Not available.

12.6 Other toxic effects: Not available.

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Sodium azide	Extraordinarily hazardous
New York	Sodium azide	A – acutely hazardous substances
New Jersey	Sodium azide	-
Pennsylvania	Sodium azide	E - Substance is on the Environmental Hazard List

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Sodium azide	26628-22-8	500	1,000	1,000	313	P105	-

[I]**SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] [I]**SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] [I]**SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV]**CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] [I]**SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI]**RCRA Code:** Resource Conservation and Recovery Act Code
[VII]**CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed**.**

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 07/28/2010
- Revision n. 01, dated 01/13/2012
- Revision n. 02, dated 06/25/2012.
- Revision n. 03, dated 09/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: The effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: no observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: Very persistent, very Bio accumulative
WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s): H300: Fatal if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx
(2) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012
(3) HSDB Hazardous Substances Databank, Sodium azide
(4) Recommendation from the Scientific Committee on Occupational Exposure Limits for sodium azide, SCOEL/SUM/51,September 2009
(5) http://apps.echa.europa.eu/registered/data/dossiers, Sodium azide
(6) ChemIDplus Lite, Sodium azide, full record
(7) http://www.ncbi.nlm.nih.gov/pubmed/12851150, Human health effects of sodium azide exposure: a literature review and analysis. Int J Toxicol. 2003 May-Jun;22(3):175-86.
(8) http://www.ncbi.nlm.nih.gov/pubmed/2671718, Sodium azide mutagenesis in mammals: inability of mammalian cells to convert azide to a mutagenic intermediate. Arenaz P1, Hallberg L, Mancillas F, Gutierrez G, Garcia S.
(9) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)
(10) http://www.bibra-information.co.uk/downloads/toxicity-profile-for-sodium-azide-1992/, Toxicity Profile for Sodium azide (1992)
(11) http://onlinelibrary.wiley.com, The MAK Collection for Occupational Health and Safety, Sodium azide
(12) International Chemical Safety Cards, Sodium azide

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® CLEANING SOLUTION

Doc. ID: SDS0009831700_EN
Revision: 03
CO: 458574
Edited on: 09/28/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® CLEANING SOLUTION**

Product Number: **0009831700**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0009831700	**CLEANING SOLUTION**	**Not classified**	**Not classified**	**1 x 500 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
CLEANING SOLUTION

Doc. ID: SDS0009831700_EN
Revision: 03
CO: 458574
Edited on: 09/28/2015

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **CLEANING SOLUTION**

Product Number: **0009831700**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200, and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulations (EC) No 1272/2008, Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	None

Safety precautions:
Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: hydrochloric acid aqueous solution.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
Hydrochloric acid (aqueous solution) *Index N. (Annex VI of CLP Reg.): 017-002-01-X* *REACh Reg. N.: 01-2119484862-27-XXXX*	231-595-7	7647-01-0 (Hydrogen chloride anhydrous)	< 0.5%	Skin Corrosion/Irritation, cat 1B STOT SE, cat.3	Skin Corr. 1B, H314 STOT SE 3, H335 *Specific Conc. Limits:* Skin Corr. 1B; H314: c ≥ 25 % Skin Irrit. 2, H315: 10 % ≤ c < 25 % Eye Irrit. 2, H319: 10 % ≤ c < 25 % STOT SE 3, H335: c ≥ 10%

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture contains one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Hydrochloric acid. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation to the mucous membranes and upper respiratory tract.
Skin: May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May cause irritation to the gastrointestinal mucous membranes.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of HCl.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection:	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed to the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
For emergency responders:	Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.
6.2 Environmental precautions	Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
6.3 Methods and material for containment and cleaning up	Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. Send to the storage waiting for disposal procedures.
6.4 Reference to other sections	See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling	Handle in a well ventilated place. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.
7.2 Conditions for safe storage, incompatibilities	Recommended temperature: store at 15-25°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.
7.3 Specific end use	*Cleaning Solution* is intended for in vitro diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

	Limit value – 8 hours		*Limit value – short term**	
	ppm	*mg/m³*	*ppm*	*mg/m³*
Hydrogen chloride (gas and aerosol mists) [(1)]				
European Union	5	8	10	15
Austria	5	8	10	15
Belgium	5	8	10	15
Denmark	5	7	5	7
France	-	-	5	7,6
Germany (AGS)	2	3	4[(a)]	6[(a)]
Germany (DFG)	2	3	4	6
Hungary	-	8	-	16
Italy	5	8	10	15
Poland	-	5	-	10[(b)]
Spain	5	7.6	10	15
Sweden	-	-	5[(b)]	8[(b)]
Switzerland	2	3,0	4	6
The Netherlands	-	8	-	15

USA-NIOSH	-	-	5[(b)]	7[(b)]
USA-OSHA	-	-	5	7
United Kingdom	1	2	5	8
Canada - Québec	-	-	5[(b)]	7,5[(b)]
ACGIH (2000) [(6)]	TLV STEL = 2ppm (ceiling). Notation A4 - not classifiable as a Human Carcinogen.			

[(a)] 15 minutes average value;
[(b)] ceiling limit value
** Short term is 15 minutes unless otherwise specified*

Community/National biological exposure limit values: not available

DNEL Values (components):

Component	***Route of exposure***	*Workers*				*Consumers*			
		Acute effects		*Chronic effects*		*Acute effects*		*Chronic effects*	
		local	*systemic*	*local*	*systemic*	*local*	*systemic*	*local*	*systemic*
Hydrogen chloride [(5)]	*Oral (mg/kg bw/day)*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m3)	*15*		*8*					

PNEC Values (components): Hydrochloric acid: It is not considered useful to calculate a PNEC for hydrochloric acid because factors such as the buffer capacity, the natural pH and the fluctuation of the pH are very specific for a certain ecosystem. [(5)]

Recommended monitoring procedures:

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Liquid	
Odor:	Not available	
Color:	Colorless	
pH:	1.2 at 20°C	Mixture
Flammability:	Aqueous solution, not expected to be flammable	
Explosive properties:	Aqueous solution, not expected to be explosive	
Oxidizing properties:	Aqueous solution, not expected to be oxidant	
Density:	0.998 g/ml at 20°C	Mixture
Solubility:	Not available	

	Water Solubility:	Miscible	Mixture
	Melting point/range:	Liquid, not applicable	
9.2	**Other information**	Not available	

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability**	The product is stable until the expiration date shown on the box and on the labels when stored at 15 – 25°C.
10.3	**Possibility of hazardous reactions**	Not foreseen.
10.4	**Conditions to avoid:**	Keep out from heat and light.
10.5	**Incompatible materials**	Bases, metals. HCl is highly corrosive to most metals; it also reacts with hydroxides, amines, and alkalis.
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may include toxic and hazardous fumes of HCl.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	May cause skin irritation.
Ingestion:	May cause irritation to the gastrointestinal mucous membranes.
Inhalation:	May cause irritation to the mucous membranes and upper respiratory tract.
Contact with eyes:	May cause serious eye irritation

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Hydrochloric acid: the main intake pathway is considered to be via the respiratory tract. Inhaled aerosol of hydrochloric acid is mainly retained on the mucous membranes of the upper respiratory airways and partially neutralized there. In principle, absorption is considered possible but because of the severe local effects is at most of secondary importance. It is assumed that dermal exposure does not lead to uptake of systemically relevant doses. Hydrochloric acid is completely dissociated. Therefore, following absorption, only chloride ions and hydrogen ions are available in the organism and there is no accumulation of HCl. Chloride ions and hydrogen ions are integrated in the organism into the well-known physiological metabolic processes. The elimination of chloride mainly proceeds with the urine and is regulated via homeostatic mechanisms because of physiologic importance as an electrolyte. [2] [3]

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	Following oral intake, *hydrochloric acid* often causes long lasting vomiting. The damaging effect is mainly determined by the concentration. Concentrated acid can very rapidly cause life threatening damage (glottic edema, perforation/strictures in the esophagus/stomach) and additional reflex cardiovascular and respiratory disorders. When 33% hydrochloric acid is swallowed, as little as 5 - 20 ml can be lethal. For the very diluted acid, the risk is reduced. For the 3.3% HCl, 238 - 277 mg/kg bw was determined to be an oral LD50 for rats.			[3]	Hydrochloric acid solution
Dermal:	LD50 (rabbit) > 5,010	mg/Kg	(no details on the concentration of the solution)		Hydrochloric acid solution
Inhalation:	LC50 values found in tests on rodents following inhalation of *hydrochloric acid* vapors were at 8.3 mg/L for 30 minutes for rats; 16.5 mg/L for 5 min and 3.2 mg/L for 30 min for mice. However, for humans it was reported that even short-term inhalation of 500 - 1000 ppm hydrogen chloride gas can cause glottic cramps or reflex respiratory and cardiac arrest.			[3]	Hydrochloric acid solution
Other data:	Not available				

Corrosion/Irritation

Skin Corrosion/Irritation — *Hydrochloric acid:* 1% aqueous solution proved to be not irritating on rabbits after 5 applications of 0.5 ml within 5 days. Hydrochloric acid 17% and 37% aqueous solutions produced severe damage to the skin of rabbits. (4)

Serious eye damage/ irritation — 0.1 ml of *Hydrochloric acid* 0.33% and 3.3% aqueous solutions proved to be not irritating and slightly irritating respectively, after an application of 0.1 ml into the conjunctival sac (observation period: 48 hours). Rabbits treated with 0.1 ml of HCl 10% solution showed severe irritation to eyes. (2)

Sensitization:

Skin sensitization: — *HCl solution*: From occupational handling, there is no indication of a sensitization of the skin. Also a test on volunteers and 2 animal experiments (maximization test on guinea pigs and mouse ear swelling test) were negative. (3)

Respiratory sensitization: — Not available.

CMR effects

Germ cell mutagenicity; — *HCl solution*: a negative result has been shown in the Ames test. A positive result, which is considered to be an artifact due to the low pH, has been obtained in a chromosome aberration test using Hamster ovary cells. The effects of low pH in *in vitro* studies are not a problem *in vivo* as the proton level is regulated systemically. (2)

Reproductive toxicity: — *HCl solution:* No reliable studies have been reported regarding toxicity to reproduction and development in animals after oral, dermal or inhalation exposure to hydrogen chloride/hydrochloric acid. No effects on the gonads were observed in a good quality 90- day inhalation study up to 50 ppm. (2)

Carcinogenesis: — Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
HCl	Not listed	Group 3 - Not classifiable as to its carcinogenicity to humans	
The other components of the mixture are not listed.			

HCl solution: no pre-neoplastic or neoplastic nasal lesions were observed in a 128-week inhalation study with male rats at 10 ppm hydrogen chloride gas. No evidence of treatment related carcinogenicity was observed either in other animal studies performed by inhalation, oral or dermal administration. In humans, no association between hydrogen chloride exposure and tumor incidence was observed. (2)

STOT –single exposure — *Hydrochloric acid solution*: Following exposure to acid vapors, irritation to the upper airways is of the greatest concern. Considering the concentration of HCl in the room air, analogous dose-effect relationships are to be assumed: 2 - 3 ppm: still no irritation to the mucous membranes but initially slight disturbing sensations possible; 5 - 7 ppm (7.6 - 10.6 mg/m³): slight irritation to the mucous membranes; 17 - 22 ppm (approx. 26.5 - 33.5 mg/m³): unbearable, difficulties in breathing, even at short-term exposure. Based on experience of older reports at workplaces, an IDLH (immediately dangerous to life or health) value of 50 ppm was derived. (3)

STOT – repeated exposure — *HCl solution:* Following repeated contact with the skin, even diluted hydrochloric acid can cause skin damage (reddening, drying, fissures, and dermatitis). The critical effect following repeated inhalative exposure is irritation to the respiratory tract. It can be derived from occupational experience that long-term exposure to distinctly increased concentrations of HCl in inhaled air can lead to an increased incidence of airway diseases (chronic bronchitis). In older reports, chronic (but apparently still tolerable) exposure was found to lead to not only airway irritations but also to gastrointestinal diseases and to typical acid-related damage of the teeth. In a 2-year study on rats, 10 ppm HCl led to hyperplasia in the larynx and trachea. From the findings in this study, it was estimated that at exposures of up to 2 ppm (even under unfavorable conditions) no effects are expected. The NOAEL for systemic toxicity has been determined to be 20 ppm for rats and mice. (2) (3)

Aspiration hazards — Not available.

Other information: — Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity	**Species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC50 (Leuciscus idus) = 862 mg/l/48 hours	(4)	HCl solution 3%
Chronic toxicity with fish:	Not available		
Acute toxicity with crustaceans:	EC50 *Daphnia magna* = 0.492 mg/l/48h at pH 5.3 (study in accordance with OECD 202)	(2)	12 N (37.2%) Hydrochloric acid
Chronic toxicity with crustaceans:	Not available		
Acute toxicity with algae:	EC50 = 0.492 mg/l/72 h at pH 5.3 (based on growth rate) (study in accordance with OECD 201)	(2)	12 N (37.2%) Hydrochloric acid
Chronic toxicity with algae:	NOEC *Selenastrum capricornutum* = 0.097 mg/l/72 h at pH 6.0 (based on growth rate, study in accordance with OECD 201)	(2)	12 N (37.2%) Hydrochloric acid
Toxicity data on soil micro- and macroorganisms:	Not available.		
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability: The physico-chemical properties indicate that *hydrogen chloride* released into the environment is distributed into the air and water. Hydrogen chloride is readily dissociated in water into hydrated protons and chloride ion. (2)

12.3 Bioaccumulation potential: *HCl:* No accumulation of hydrogen chloride *per se* in living organisms is expected due to its high solubility and dissociation properties. (2)

12.4 Mobility in soil: Not available.

12.5 Results of PBT and vPvB assessment Chemical Safety Report and PBT assessment: not performed.

12.6 Other toxic effects: Hydrochloric acid solution may cause adverse effects to the environment due to reduction in pH. The resulting pH of the receiving water depends on its buffer capacity and the amount of HCl. In general, mortality can be observed at pH values lower than 5. (4)

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Classified for transport in accordance with ADR/RID, IMDG, and IATA regulations:

UN number:	**1789**
Pictogram	

Road transport		**Rail transport**	
Proper shipping name:	Hydrochloric Acid Solution	Proper shipping name:	Hydrochloric Acid Solution
ADR/RID class:	8	ADR/RID class:	8
Packaging group:	III	Packaging group:	III
Classification code:	C1	Classification code:	C1
ADR label:	8	ADR label:	8
Limited Quantity:	5 L	Limited Quantity:	5 L
N° identification hazard:	80	N° identification hazard:	80
Code restriction tunnel:	(E)		

Marine transport		**Air transport**	
Proper shipping name:	Hydrochloric Acid Solution	Proper shipping name:	Hydrochloric Acid Solution
IMDG class:	8	IATA class:	8
Packaging group:	III	Packaging group:	III
IMDG label:	8	IATA label:	Corrosive
Limited Quantity:	5 L	Precautions for transport:	*Passenger And Cargo* (Limited Quantity): P.I. = Y841, Max net q.ty per pack = 1 L; *Passenger And Cargo:* P.I. = 852, Max net q.ty per pack = 5 L; *Cargo Only*: P.I. = 856, Max net q.ty per pack = 60 L;
EmS	F-A, S-B	ERG Code:	*8L*
Marine pollutant:	NO	Special Provision:	A803

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Hydrogen chloride	Extraordinarily hazardous
New York	Hydrochloric acid	-
New Jersey	Hydrochloric acid	Corrosive
Pennsylvania	Hydrochloric acid	E - Substance is on the Environmental Hazard List

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	Hydrochloric acid
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Hydrochloric acid	-	-	-	5,000	313 hydrochloric acid (aerosol forms only)	-	15,000 hydrochloric acid (conc. 37% or greater)

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 12/03/2010.
- Revision n. 01, dated 06/08/2011.
- Revision n. 02, dated 07/18/2012.
- Revision n. 03, dated 09/28/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency

IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: no observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: very Persistent, very Bio accumulative
WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s): H319: Causes serious eye irritation.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H335: May cause respiratory irritation.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx
(2) UNEP Publications, OECD SIDS Initial Assessment Report for SIAM 15, Boston, USA, 22-25th October, 2002, Hydrogen chloride
(3) GESTIS Substance database, Hydrochloric acid solution
(4) IUCLID file, Hydrogen Chloride
(5) Hydrogen chloride, Registration dossier, available at: http://apps.echa.europa.eu/registered/data/dossiers/DISS-a210a35e-757f-6b38-e044-00144f67d031/AGGR-ef798dad-6fa1-4bf8-8ad7-b9fafb7464c3_DISS-a210a35e-757f-6b38-e044-00144f67d031. html#AGGR-ef798dad-6fa1-4bf8-8ad7-b9fafb7464c3
(6) ACGIH 2012, TLVs and BEIs based on the Documentation of the Threshold Limit Values for chemical substances and Physical Agents & Biological Exposure Indices

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® FACTOR DILUENT

Doc. ID: SDS0009757600_EN
Revision: 04
CO: 458649
Edited on: 09/29/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® FACTOR DILUENT**

Product Number: **0009757600**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0009757600	**FACTOR DILUENT**	**Not classified**	**Not classified**	**1 x 100 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **FACTOR DILUENT**

Product Number: **0009757600**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
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E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200, and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	None

Safety precautions:
Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: aqueous solution containing inorganic components.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
Sodium azide *Index N. (Annex VI of CLP Reg.): 011-004-00-7*	247-852-1	26628-22-8	< 0.07 %	Acute Toxicity – Oral, cat. 2 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture contains one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Sodium azide. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation.
Skin: May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May be harmful.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of NOx, Na2O, HCl.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed to the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 15-25°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

7.3 Specific end use *FACTOR DILUENT* is intended for in vitro diagnostic use**.** Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

	Limit value – 8 hours	*Limit value – short term*
Sodium azide [(1)(2)]		
European Union [(12)]	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
Austria	0,1 mg/m³	0,3 mg/m³
Belgium	0,1 mg/m³	0,3 mg/m³
Denmark	0,1 mg/m³	0,2 mg/m³
France	0,1 mg/m³ - Restrictive statutory limit value	0,3 mg/m³ - Restrictive statutory limit value
Germany (AGS)	0,2 mg/m³	0,4 mg/m³
Germany (DFG)	0,2 mg/m³ - inhalable aerosol	0,4 mg/m³ - inhalable aerosol
Hungary	0,1 mg/m³	0,3 mg/m³
Italy	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
New Zealand		0,29 mg/m³; 0,11 ppm - ceiling limit value
Poland	0,1 mg/m³	0,3 mg/m³
Spain	0,1 mg/m³	0,3 mg/m³
Switzerland	0,2 mg/m³ - inhalable aerosol	0,4 mg/m³ - inhalable aerosol
United Kingdom	0,1 mg/m³ (skin)	0,3 mg/m³ (skin)
The Netherlands	0,1 mg/m³	0,3 mg/m³

Canada – Québec	-	0,3 mg/m³; 0.11 ppm – ceiling value
Canada – Ontario	-	0.29 ppm – ceiling limit value
	-	0.11 ppm – ceiling limit value as HN_3
USA – NIOSH	-	0.1 ppm – ceiling limit value (as HN3) 0,3 mg/m³ – ceiling limit value (as NaN3)
ACGIH	-	0.29 mg/m³ –ceiling (as Sodium azide) 0.11 ppm – ceiling (as Hydrazoic acid vapor)

Community/National biological exposure limit values: Not established.

DNEL values (components): Not established.

PNEC values (components): Not established.

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Liquid	
Odor:	Not available	
Color:	Colorless, clear	
pH:	Not available	Mixture
Flammability:	Aqueous solution, not expected to be flammable	
Explosive properties:	Aqueous solution, not expected to be explosive	
Oxidizing properties:	Aqueous solution, not expected to be oxidant	
Density:	not available	
Solubility:	not available	
Water Solubility:	Soluble	
Melting point/range:	Liquid, not applicable	

9.2 Other information

Miscibility:	Miscible	Mixture

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability**	The product is stable until the expiration date shown on the box and on the labels when stored at 15 –25 °C.
10.3	**Possibility of hazardous reactions**	Not foreseen.
10.4	**Conditions to avoid:**	Keep away from heat and light.
10.5	**Incompatible materials**	Strong oxidising agents, acids, alkalis, heavy metals and their salts. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may include toxic and hazardous fumes of NOx, Na2O, HCl.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	Prolonged or repeated skin contact may cause irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Contact with eyes:	May cause irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Sodium azide is rapidly absorbed from the respiratory and gastrointestinal tract, and from injection sites. It is also rapidly absorbed by the lungs, and through the skin. The degree of skin penetration via undamaged skin is not clear. The azide anion appeared within 5 min in the plasma of rats following oral administration of 40 mg/kg sodium azide. After 24 h, no more azide could be detected in either plasma or tissue. Sodium azide penetrates the blood-brain barrier and is mainly metabolized in the liver. Its main metabolite in the liver is nitric oxide. Azide anions may be metabolized to nitric oxide (NO) also in the CNS. In aqueous solution, it rapidly transforms into hydrazoic acid, which may be responsible for the irritating effects attributed to sodium azide. Following oral administration of 40 mg/kg sodium azide, no sodium azide was detectable in the feces or in exhaled air and only 7.9 µg were excreted in the 24 h urine.[3][4][5]

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) = 27	mg/kg		[6]	Sodium azide
Dermal:	In the study of Potocar et al. (1985), 3 surviving animals were exposed to 500-1000 mg/kg sodium azide for 1 hour and then to half of that dose for three additional hours on their skins. These data do not support the dermal lethal dose (LD) of sodium azide for rabbits of 18-21 mg/kg, based on a Bassendowska and Kowalski (1961) dermal irritation study, where a single rabbit, exposed to 60 mg substance via the skin, died after 6 hours. Non classified in accordance with the opinion of the European scientific committee.			[4]	Sodium azide
Inhalation:	LC50 (rat) = 37	mg/m^3		[6]	Sodium azide
Other data:	The most commonly reported health effect from azide exposure is hypotension, almost independent of route of exposure. Fatal doses occur with exposures of > or =700 mg (10 mg/kg). Nonlethal doses ranged from 0.3 to 150 mg (0.004 to 2 mg/kg). Onset of hypotension within minutes or in less than an hour is indicative of a pharmacological response and a benign course. Hypotension with late onset (>1 hour) constitutes an ominous sign for death.[7]				

Corrosion/Irritation

Skin Corrosion/Irritation	*Sodium azide:* Dermal (semi-occlusive and occlusive) exposure to 0.5 g/patch solid sodium azide for 1 hour did not produce signs of local irritation in rabbits, whereas exposure for 4 hours was corrosive.[4] In an in vitro Skin Irritation Reconstructed Human Epidermis (RhE) Test Method (9 September 2009), sodium azide was nonirritant to skin. [5] Non classified in accordance with the opinion of the European scientific committee.
Serious eye damage/ irritation	*Sodium azide:* In a Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (September, 2009) was not considered to be an eye irritant. [5]

Sensitization:

Skin sensitization: *Sodium azide:* In a Mouse local lymph node assay (LLNA) (OECD Guideline 429), sodium azide was not a skin sensitizer. (5)

Respiratory sensitization: Not available.

CMR effects

Germ cell mutagenicity: *Sodium azide*: is highly mutagenic in many plant and bacterial species but marginally mutagenic in mammalian cells. Sodium azide was mutagenic in Salmonella typhimurium strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98. Mutagenicity as observed in bacteria is not relevant for mammals, because of the specific metabolism of sodium azide in bacteria. The existing data support the conclusion that azide may be further modified in mammalian cells to an intermediate that is not genotoxic. (4)(8) Negative in a Chromosomal aberration test. In a Cytogenetic tests with Chinese hamster ovary cells, Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations. (9) No studies in mammals are available to adequately assess germ cell effects. (6)

Reproductive toxicity: *Sodium azide*: Insufficient data are available for an assessment of the reproductive toxicity.(11)

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

Sodium azide: Two long-term oral studies in rats provided no convincing evidence of carcinogenicity, although in both cases the suitability of the test doses has been questioned. At concentrations of 5 and 10 mg/kg sodium azide there was no evidence of carcinogenicity in rats during a 2-year study.(10)

STOT –single exposure *Sodium azide* is not an irritant but is rapidly hydrolyzed to hydrazoic acid in the acidic environment of mucous membranes and the tracheobronchial tree. (4) Hydrazoic acid vapor in concentrations of 0.5 ml/m^3 (0.9 mg/m^3) or more caused irritation of the nasal mucosa. Irritation of the conjunctiva has also been described. (11) Non classified in accordance with the opinion of the European scientific committee.

STOT – repeated exposure *Sodium azide:* Repeated oral administration caused brain and lung damage in rats, but no such effects have apparently been seen in a corresponding mouse study.(10) Non classified in accordance with the opinion of the European scientific committee.

Aspiration hazards Not available.

Other information: The occupational neuropsychotoxicology of sodium azide was investigated annually, for three years in 41 sodium azide exposed workers in a chemical production plant, compared to 42 unexposed ones working in the same plant. Exposed workers presented significantly more acute symptoms of exposure than unexposed workers. Symptoms reported included headache, vertigo, nausea, fatigue, cardiac palpitations, irritated or red eyes. The only recurring chronic symptom was trembling of the hands. No psychological or neuropsychological tests differentiated the exposed from the unexposed group. (4)

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity	**Species, media, units, test duration and test conditions**		**Related to**
Acute toxicity with fish:	LC_{50} *Lepomis macrochirus* = 0.7 mg/l/96 hours	(3)	Sodium azide
Chronic toxicity with fish:	Not available.		
Acute toxicity with crustaceans:	EC_{50} *Daphnia pulex* = 4.2 mg/l/96 hours	(3)	Sodium azide
Chronic toxicity with crustaceans:	Not available.		
Acute toxicity with algae:	EC50 *Pseudokirchneriella* = 0.35 mg/l/96 hours	(5)	Sodium azide
Chronic toxicity with algae:	Not available.		
Toxicity data on soil micro- and macroorganisms:	Not available.		

	Toxicity data on birds, bees and plants:	In a bioassay comparable to OECD guideline 208 with slight restrictions, 10 ppm sodium azide in the soil significantly reduced germination and growth in plant species tested, whereas the growth was mostly affected at concentrations above 5 ppm, exhibiting a delay in plant germination. After dissipation of sodium azide normal growth proceeded. [5]	Sodium azide
12.2	**Persistency and degradability:**	Biodegradability is not applicable.	
12.3	**Bioaccumulation potential:**	Not available.	
12.4	**Mobility in soil:**	The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures. [7]	
12.5	**Results of PBT and vPvB assessment:**	Not available.	
12.6	**Other toxic effects:**	Not available.	

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Sodium azide	Extraordinarily hazardous
New York	Sodium azide	A – acutely hazardous substances
New Jersey	Sodium azide	-
Pennsylvania	Sodium azide	E - Substance is on the Environmental Hazard List

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Sodium azide	26628-22-8	500	1,000	1,000	313	P105	-

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed**.**

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 07/28/2010.
- Revision n. 01, dated 08/12/2011.
- Revision n. 02, dated 07/16/2012.
- Revision n. 03, dated 09/09/2015.
- Revision n. 04, dated 09/29/2015. Main changes are in sections 15.1 and 16, updating information per the most recent version of REACH.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population

LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)

LOEL: Lowest Observed Effect Level

MADL: Maximum Allowable Daily (or Dose) Level

NOAEL: No Observed Adverse Effect Level)

NOEC: no observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment

PBT: Persistent, Bio accumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: very Persistent, very Bio accumulative

WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s): H300: Fatal if swallowed.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx

(2) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012

(3) HSDB Hazardous Substances Databank, Sodium azide

(4) Recommendation from the Scientific Committee on Occupational Exposure Limits for sodium azide, SCOEL/SUM/51,September 2009

(5) http://apps.echa.europa.eu/registered/data/dossiers, Sodium azide

(6) ChemIDplus Lite, Sodium azide, full record

(7) http://www.ncbi.nlm.nih.gov/pubmed/12851150, Human health effects of sodium azide exposure: a literature review and analysis. Int J Toxicol. 2003 May-Jun;22(3):175-86.

(8) http://www.ncbi.nlm.nih.gov/pubmed/2671718, Sodium azide mutagenesis in mammals: inability of mammalian cells to convert azide to a mutagenic intermediate. Arenaz P1, Hallberg L, Mancillas F, Gutierrez G, Garcia S.

(9) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)

(10) http://www.bibra-information.co.uk/downloads/toxicity-profile-for-sodium-azide-1992/, Toxicity Profile for Sodium azide (1992)

(11) http://onlinelibrary.wiley.com, The MAK Collection for Occupational Health and Safety, Sodium azide

(12) International Chemical Safety Cards, Sodium azide

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® HIGH ABNORMAL CONTROL ASSAYED

Doc. ID: SDS00020003310_EN
Revision: 02
CO: 458507
Edited on: 09/25/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® HIGH ABNORMAL CONTROL ASSAYED**

Product Number: **0020003310**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020003300	**HIGH ABNORMAL CONTROL ASSAYED**	**Not classified**	**Not classified**	**10 x 1 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HIGH ABNORMAL CONTROL ASSAYED

Doc. ID: SDS00020003310_EN
Revision: 02
CO: 458507
Edited on: 09/25/2015

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **HIGH ABNORMAL CONTROL ASSAYED**

Product Number: **0020003300**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:

+44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:

This product is not hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	None
Precautionary statement(s):	None
Other labeling details:	**Up to 100% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

Safety precautions:

Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.
Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: powder containing organic and inorganic compounds, human and animal source material.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS 2015)	Classification 1272/2008/EC
2-pyridinethiol-1-oxide sodium salt (sodium pyrithione; sodium omadine)	223-296-5	3811-73-2	< 0.0001 %	Acute Toxicity – Oral, cat. 4 Acute Toxicity – Dermal, cat. 4 Acute Toxicity – Inhalation, cat. 4 Skin Corrosion/Irritation, cat.2 Eye damage/Eye Irritation, cat.2A Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox. 4, H302 Acute Tox. 4, H312 Acute Tox. 4, H332 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Acute 1, H400 (M =100) Aquatic Chronic 1, H410 (M= 10)

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation.
Skin: May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May be harmful.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO_2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, SOx.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 2-8°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *High Abnormal Control Assayed* is intended for in vitro diagnostic use. The product contains bovine material and human source material. The human source material tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled. This product, as with all human or animal based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

Sodium pyrithion[(1)]	*Limit value – 8 hours*	*Limit value – short term*
Austria	1 mg/m³	4 mg/m³
Denmark	1 mg/m³	2 mg/m³
Germany (AGS)	1 mg/m³- inhalable aerosol	2 mg/m³ - 15 minutes average value
Germany (DFG)	1mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol
Switzerland	1mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol

Community/National biological exposure limit values: Not established.

DNEL values (components): Not established.

PNEC values (components): Not established.

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Powder, cake	
Odor:	Odorless	
Color:	Off white	
pH:	Neutral	Mixture
Flammability:	Not available	
Explosive properties:	Not available	
Oxidizing properties:	Not available	
Density:	Not available	
Solubility:	Not available	
Water Solubility:	Soluble	
Melting point/range:	Not available	

9.2 Other information Not available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity	This mixture is considered not reactive under the normal conditions of the usage.
10.2 Chemical stability	The product is stable until the expiration date shown on the box and on the labels when stored at 2 –8°C.
10.3 Possibility of hazardous reactions	Not foreseen.
10.4 Conditions to avoid:	Keep out from heat, water, humidity and light.
10.5 Incompatible materials	Oxidizing agents, reducing agents.
10.6 Hazardous decomposition products:	Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	Prolonged or repeated skin contact may cause irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Contact with eyes:	May cause irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Sodium pyrithione (2-pyridinethiol-1-oxide sodium salt) is readily absorbed from the gastrointestinal tract and through the skin. In rats was rapidly absorbed, metabolized, and excreted at all dosing levels. There was no evidence of bioaccumulation of Sodium omadine or its metabolites in the tissues. The urine is the major route of excretion of Sodium omadine (73-85% of the dose); the feces are only a minor route of excretion (5-12% of the dose). Sodium omadine and its metabolites were not excreted in expired air. The major metabolite in rat urine was 2-pyridinethiol-1-oxide-S-glucuronide. [2]

Acute toxicity	**Value**	**m.u.**	**Effects**	**Related to**
Oral:	LD50 (rat) =1,500	mg/Kg		[2] Sodium omadine 40%
	LD50 (rat) =750	mg/Kg		[3] sodium pyrithione
Dermal:	LD50 (rat) = 1,800	mg/Kg		[2] Sodium omadine 40%
	LD50 (rat) = 700	mg/Kg		[3] sodium pyrithione.
Inhalation:	LC50 (rat) = 1.08	mg/l/4h		[2] Sodium omadine 40%
	LC50 (rat) = 1.1	mg/l/4h		[3] sodium pyrithione.
Other data:	not available			

Corrosion/Irritation

Skin Corrosion/Irritation	*Sodium pyrithione:* A single dose applied occlusively for 4 hours to the skin of rabbits as a 40% aqueous solution caused mild edema and erythema which had regressed after 72 hours. [4]
Serious eye damage/ irritation	*Sodium pyrithione:* Instillation of a 40 % solution (0.1 ml) into the eyes of rabbits caused mild, transient clouding of the cornea in 2/6 animals 24 hours after application. In all animals mild reddening of the conjunctiva developed and in 2/6 animals had not regressed after 72 hours. Conjunctival reddening was also observed after application of the substance in powder form (10 mg). [4]

Sensitization:

Skin sensitization:	*Bovine serum albumin (BSA),* which is present in bovine plasma, could develop allergic skin reactions in laboratory workers after dealing with BSA powder. Based on the available data, the criteria for classification are not satisfied. *Sodium pyrithione* was not found to be a dermal sensitizer in the tests conducted. [2]
Respiratory sensitization:	*Bovine serum albumin (BSA),* which is present in bovine plasma, could develop allergic reactions in laboratory workers after dealing with BSA powder. It is reported a case of occupational asthma and rhinitis in a laboratory worker caused by the inhalation of 100% BSA powder. The patient had a high serum-spercific IgE level to BSA, and experienced severe systemic reactions, including eye itching, conjunctivitis, rhinorrhea, nasal obstruction, sneezing, shortness of breath, bronchospasm and decreased blood pressure. It was suggested an IgE-mediated response as the pathogenic mechanism. [6] Based on the available data, the criteria for classification are not satisfied.

CMR effects

Germ cell mutagenicity:	*Sodium pyrithione:* Genotoxic effects of the substance could not be demonstrated in the Salmonella mutagenicity test, in the HPRT (hypoxanthine guanine phosphoribosyl transferase) test or in the test for DNA repair in rat hepatocytes. However, because the substance is cytotoxic, only low concentrations could be tested. Negative results were also obtained in vivo in the micronucleus test. [4]
Reproductive toxicity:	*Sodium pyrithione:* Reproductive toxicity is not observed, either after dermal application to rats or rabbits or after oral administration to rats. Embryotoxicity develops in rats but not in rabbits after maternally toxic doses of sodium pyrithione. [4]

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

Sodium pyrithione is not carcinogenic either after dermal application to mice or after oral administration to rats. (4)

STOT –single exposure There are no reports of toxic effects of single exposures of persons to *sodium pyrithione*. (4)

STOT – repeated exposure *Sodium pyrithione:* No signs of toxic effects were observed in nine male workers who had been employed for between 2 and 13 years in the production of sodium pyrithione. In the 90 day dermal toxicity study, rats were given daily doses of Sodium omadine at levels of 0, 5, 15 or 50 mg/kg/day. There was no evidence of dose-related dermal irritation. The NOEL was 15 mg/kg/day in males and 5 mg/kg/day in females.(2) Sodium omadine (41.41% and 40.5% purity) in 40% aqueous solution was administered in water by gavage to groups of 5 male and 5 female Cynomolgus monkeys for 1 year at dose levels of 0, 5, 25, or 150 mg/kg/day. No evidence of toxicity was seen at the 5 mg/kg/day dose other than emesis in some monkeys. The NOAEL was 5 mg/kg/day.(2)

Aspiration hazards Not available.

Other information: *Sodium pyrithione:* Although no signs of neurotoxic effects were seen in monkeys even after intubation of relatively high doses for a period of 1 year, the possibility remains that such effects could develop in man after high level exposures. (4)

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1	**Toxicity**	**species, media, units, test duration and test conditions.**		**Related to**
	Acute toxicity with fish:	LC_{50} *Lepomis macrochirus* = 6.6-8 µg/l/96 hours	(3)	sodium omadine
	Chronic toxicity with fish:	Not available		
	Acute toxicity with crustaceans:	EC50 water flea Daphnia = 0.022 mg/l/48hours	(5)	sodium omadine
	Chronic toxicity with crustaceans:	Not available		
	Acute toxicity with algae:	ErC50 = 0.46 mg/l/72 hours	(5)	sodium omadine 40.2%
	Chronic toxicity with algae:	NOErC =0.08 mg/L/72 h	(5)	sodium omadine 40.2%
	Toxicity data on soil micro- and macroorganisms:	EC50 = 120 mg/L/3 h	(5)	sodium omadine 41%
	Toxicity data on birds, bees and plants:	Mallard duck 8 day dietary LC50 = 10033 ppm Bobwhite quail 8 day dietary LC50 = 3075 ppm	(3)	sodium omadine 40%
		Mallard duck acute oral LD50 = 92 mg/kg Bobwhite quail acute oral LD50 = 200 mg/kg	(3)	sodium omadine 94.9%
12.2	**Persistency and degradability:**	Sodium pyrithione (40.8% sol.) is readily biodegradable. (5)		
12.3	**Bioaccumulation potential:**	Not available.		
12.4	**Mobility in soil:**	Not available.		
12.5	**Results of PBT and vPvB assessment**	Not available.		
12.6	**Other toxic effects:**	Not available.		

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	No component listed	
Pennsylvania	No component listed	

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 11/24/2010.
- Revision n. 01, dated 07/05/2012.
- Revision n. 02, dated 09/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: The effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: No observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bio accumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: Very Persistent, very Bio accumulative
WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s):

H302: Harmful if swallowed
H312: Harmful in contact with skin.
H332: Harmful if inhaled.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx

(2) UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Office of Prevention, Pesticides And Toxic Substances, Registration Eligibility Decision(RED) Sodium Omadine, EPA 738-R-95-031, January 1996

(3) Sodium omadine® 40% aq. Sol. Industrial fungicide/bactericide, SDS of the supplier up the supply chain

(4) The MAK Collection for Occupational Health and Safety, Volume 10, Sodium pyrithione, The MAK Collection for Occupational Health and SafetyPublished Online: 31 JAN 2012

(5) Sodium pyrithione, Registration Dossier, ECHA, http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea00f77-8e69-65ae-e044-00144f67d031/DISS-9ea00f77-8e69-65ae-e044-00144f67d031_DISS-9ea00f77-8e69-65ae-e044-00144f67d031.html

(6) http://e-aair.org - Allergy, Asthma and Immunology Research (AAIR) 2009, October, Occupational asthma caused by inhalation of bovine serum albumin powder, Case report

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
HEMOSIL® NORMAL CONTROL ASSAYED

Doc. ID: SDS00020003110_EN
Revision: 02
CO: 458507
Edited on: 09/25/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **HEMOSIL® NORMAL CONTROL ASSAYED**

Product Number: **0020003110**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020003100	**NORMAL CONTROL ASSAYED**	**Not classified**	**Not classified**	**10 x 1 ml**

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

Instrumentation Laboratory
A Werfen Company

SAFETY DATA SHEET
NORMAL CONTROL ASSAYED

Doc. ID: SDS00020003110_EN
Revision: 02
CO: CO: 458507
Edited on: 09/25/2015

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **NORMAL CONTROL ASSAYED**

Product Number: **0020003100**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulation (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

According to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	none
Signal word(s):	none
Hazard statement(s):	none
Precautionary statement(s):	none
Other labeling details:	**≈ 100% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: powder containing organic components, human plasma.

3.1 Hazardous components: no known hazardous ingredients.

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion:	If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.
Inhalation exposure:	If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.
Contact with skin:	Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.
Contact with eyes:	Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute:	Inhalation: May cause irritation. Skin: May be irritant for skin. Eyes: May cause irritation. Ingestion: may be harmful.
Delayed:	Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring:	Not foreseen.
Antidotes, if known:	Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray or regular foam, CO_2, dry powder.
Unsuitable extinguishing media:	Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:	Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, SOx, HCl.

5.3 Advice for firefighters

Protective actions:	Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.
Equipment for self-protection:	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
For emergency responders:	Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.
6.2 Environmental precautions	Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3	**Methods and material for containment and cleaning up**	Collect spilled material in containers. Where appropriate, moisten to prevent the dispersion of dust, absorb with inert materials and wash the area with plenty of water. Send to the storage waiting for disposal procedures.
6.4	**Reference to other sections**	See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1	**Precautions for safe handling**	Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.
7.2	**Conditions for safe storage, incompatibilities**	Recommended temperature: store at 2 - 8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.
7.3	**Specific end use**	*Normal Control Assayed* is intended for in vitro diagnostic use. This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values: not available

Community/National biological exposure limit values: not available

DNEL values (components): Not available

PNEC values (components): Not available.

Recommended monitoring procedures:

The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you can not prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	Related to
Appearance:	Powder, cake	
Odor:	Odorless	
Color:	Off white	
pH:	Not available	
Flammability:	Not available	
Explosive properties:	Not available	
Oxidizing properties:	Not available	
Density:	Not available	Mixture
Solubility:	Not available	
Water Solubility:	Soluble	Mixture
Melting point/range:	Not available	

9.2 Other information

Miscibility: Miscible

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.3 Possibility of hazardous reactions Not foreseen.

10.4 Conditions to avoid: Keep out from hot temperature, humidity and light.

10.5 Incompatible materials Oxidizing agents.

10.6 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx, HCl.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal: May cause irritation.

Ingestion: Ingestion may cause irritation to the gastrointestinal mucous membranes.

Inhalation: Inhalation of the product may cause irritation to respiratory ways.

Contact with eyes: May cause eye irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion): not available

Acute toxicity	Value	m.u.	Effects	Related to
Oral:	Not available			
Dermal:	Not available			
Inhalation:	Not available			
Other data:	Not available			

Corrosion/Irritation

Skin Corrosion/Irritation	Not available
Serious eye damage/ irritation	Not available

Sensitization:

Skin sensitization:	Not available
Respiratory sensitization:	Not available

CMR effects

Germ cell mutagenicity: Not available

Reproductive toxicity: Not available

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
The components of the mixture are not listed.			

STOT –single exposure Not available.

STOT – repeated exposure Not available.

Aspiration hazards Not available.

Other information: Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated.

12.1 Toxicity	**Species, media, units, test duration and test conditions.**	**Related to**
Acute toxicity with fish:	Not available	
Chronic toxicity with fish:	Not available	
Acute toxicity with crustaceans:	Not available	
Chronic toxicity with crustaceans:	Not available	
Acute toxicity with algae:	Not available	
Chronic toxicity with algae:	Not available.	
Toxicity data on soil micro- and macroorganisms:	Not available.	
Toxicity data on birds, bees and plants:	Not available.	
12.2 Persistency and degradability:	Not available	
12.3 Bioaccumulation potential:	Not available	
12.4 Mobility in soil:	Not expected to adsorb on soil.	
12.5 Results of PBT and vPvB assessment	Chemical Safety Report and PBT assessment: not performed.	
12.6 Other toxic effects:	Not available	

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	No component listed	
Pennsylvania	No component listed	

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] [I] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] [I] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] [I] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 07/28/2010.
- Revision n. 01 dated 06/26/2012.
- Revision n. 02 dated 09/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

AIHA: American Industrial Hygiene Association

ADR: Agreement concerning the carriage of dangerous goods by Road

BCF: Bioaccumulative factor

BEI : Biological Esposure Indices

CAS: Chemical Abstract Service (division of the American Chemical Society

CLP: Classification, Labeling and Packaging

DNEL: Derived No-Effect Levels

EC50: The effect concentration associated with 50% response.

EINECS: European Inventory of Existing Commercial Substances

EPA: US Environmental Protection Agency

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association Code

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal Concentration to 50 % of a test population

LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)

LOEL: Lowest Observed Effect Level

MADL: Maximum Allowable Daily (or Dose) Level

NOAEL: No Observed Adverse Effect Level)

NOEC: No observed effect concentration means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment

PBT: Persistent, Bio accumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: Very Persistent, very Bio accumulative

WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008: none

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references: none

MSDS1609

Hg Absorb®
MATERIAL SAFETY DATA SHEET

SECTION I: MANUFACTURER INFORMATION

Lab Safety Supply, Inc.
PO Box 1368
Janesville, WI 53547
(608) 754-2345

Date Issued: 05/16/90
Date Reviewed: 05/10/10
Phone Number: (800) 356-2501
Emergency Number: (800) 255-3924

Assembled for LSS per LSS specifications by:
Kandu Industries
Janesville, WI

SECTION II: MATERIAL IDENTIFICATION & INFORMATION

Components CAS Number	%	OSHA PEL	ACGIH TLV	Limits Recommended
Granular Zinc *(7440-66-6)*	94–96	N/A	N/A	5mg/m³ respirable dust 15mg/m³ total dust
Citric Acid *(77-92-9)*	4–6	N/A	N/A	5mg/m³ respirable dust 15mg/m³ total dust

SECTON III: PHYSICAL/CHEMICAL CHARACTERISTICS

Boiling Point: N/A
Vapor Pressure: N/A
Vapor Density (Air=1): N/A
Solubility in Water: Moderate
Appearance and Odor: Gray granular solid

Specific Gravity (H_2O=1): Bulk density 2.35gm/cc
Melting Point: N/A
Evaporation Rate: N/A
Water Reactive: Hydrogen may be released

SECTION IV: FIRE & EXPLOSION DATA

Flash Point: N/A
Auto Ignition Temperature: N/A
Flammability Limits in Air (% by volume): N/A

LEL: N/A
UEL: N/A

Extinguishing Media:
CO_2, or dry chemical (DO NOT use water. Water will react violently with molten material.)
Special Fire Fighting Procedures: N/A
Unusual Fire & Explosion Hazards: Zinc dust mixed with sulfur dust may explode.

SECTION V: REACTIVITY HAZARD DATA

Stability: Stable
Materials to Avoid: Oxidizing agents, acids, bases, halogens, reducing agents, amines, chlorinated solvents and sulfur.
Hazardous Decomposition Products: May release CO and/or CO_2.
Hazardous Polymerization: N/A
Conditions to Avoid: N/A

SECTION VI: HEALTH HAZARD DATA

Primary Routes of Entry: Inhalation

Carcinogen Listed in: N/A

Health Hazards:
Acute irritation to eyes, nose, throat, metallic taste in mouth, flu like symptoms. Chronic chromosomal anomalies in leukocytes reported, arthritic lameness and inflammation of gastro-intestinal tract reported in animal studies.

Signs and Symptoms of Exposure:
Irritation of nose, throat and eyes.

Medical Conditions Generally Aggravated by Exposure:
N/A

EMERGENCY FIRST AID PROCEDURES—Seek medical assistance for further treatment.
Eye contact: Flush eyes with plenty of water for at least 15 minutes.
Skin contact: Flush with plenty of water.
Inhalation: Remove to fresh air, seek medical attention immediately.
Ingestion: Dilute with plenty of water and seek medical attention immediately.

SECTION VII: CONTROL AND PROTECTIVE MEASURES

Respiratory Protection:
Use NIOSH approved particulate respirator at total dust levels over 15mg/m³.

Protective Gloves:
Polyethylene, rubber or PVC

Eye Protection:
Safety glasses recommended.

Other Protective Clothing and Equipment:
None required under normal use.

Ventilation to be Used:
Mechanical (general)

Hygienic Work Practices:
Wash hands after use.

SECTION VIII: PRECAUTIONS FOR SAFE HANDLING AND USE

Steps To Be Taken if Material is Spilled or Released:
Sweep up material and place in waste disposal container.

Waste Disposal Methods:
Mercury free material may be containerized and disposed of in a licensed landfill. Dispose of mercury containing material in accordance with local, state and federal regulations for hazardous waste.

Precautions to Take in Handling and Storage:
Store in cool dry place, away from incompatible materials.

Other Precautions and/or Special Hazards:
N/A

NFPA Rating:
Health 0 Flammability 1 Reactivity 1 Special N/A

HealthLink® A Family of Medical Products
Joining Forces to Serve the Healthcare Community
CLOROX HEALTHCARE®

Safety Data Sheet

Hydrochloric Acid 10%

Revision Date: 6/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Hydrochloric Acid, 10%
Product code: 400501

Supplier: HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM

Synonym: None.
Material uses: Laboratory Reagent.
Validation date: 1/15/2015
In case of emergency: 800-424-9300 CHEMTREC (USA)
24 Hours/Day: 7 Days/Week

2. HAZARDS IDENTIFICATION

GHS Classification

Skin Corrosion (Category 1A), H314	H314 Cause severe skin and eye damage
Serious Eye Damage (Category 1), H318	H318 Causes serious eye damage

GHS Label Elements

Pictogram
Signal Word Danger!

Health Statement(s):
H318: Causes serious eye damage (Cat 1)
H314: Causes severe skin burns and eye damage (Cat 1)
H370: Causes damage to organs (Cat 1)
H305: May be harmful if swallowed and enters airways (Cat 2)

Precautionary statement(s):
P280: Wear protective gloves/ eye protection/ face protection.
P305+351+338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Potential Acute Health Effects:
Very hazardous in case of contact with eye, skin, ingestion and inhalation. Liquid or spray mist may produce tissue damage especially mucous membranes of eyes, mouth and respiratory tract. Will burn eyes and skin on contact. Respiratory track characterized by coughing, choking and shortness of breath. Inflammation of eyes results in redness, watering and itching. Skin contact results in scaling, redness or blistering.

Potential Chronic Helath Effects:
Carcinogenic Effects, NA; Mutagenic Effects, NA; Teratogenic Effects, NA; Developmental Toxicity, NA. May be toxic to kidneys, liver, mucous membranes, repiratory tract, skin and teeth.

Target Organs
Respiratory Tract

NFPA Rating	**HMIS Classification**
Health hazard: 3	Health hazard: 3
Fire: 0	Flammability: 0
Reactivity Hazard: 1	Physical hazards: 1

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	**CAS number**	**% by volume**
Hydrochloric Acid	7647-01-0	~ 10
Water	7732-18-5	~ 90

4. FIRST AID MEASURES

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with water for 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention immediately.

Skin contact: Flush skin with water for 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.

Inhalation: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.

Ingestion: Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

5. FIRE-FIGHTING MEASURES

Flammability of the product: Non-**F**lammable

Extinguishing media: Use suitable media for surrounding materials. If water use fog spray, avoid direct stream.

Special exposure hazards: Avoid contact with metal, hydrogen chloride gas can react with aluminum, tin, lead, zinc

Decomposition products: Decomposition products: hydrogen gas, hydrogen chloride gas

Special protective equipment for fire-fighters: Use self-contained breathing apparatus with water spray.

Explosion hazards: hydrogen gas can form in fire situation which is flammable.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary and unprotected personnel from entering area. Avoid breathing vapors. Provide adequate ventilation. Do not touch or walk through spilled material. Beware of vapors accumulating to form explosive hydrogen gas mixtures. Full personal safety equipment (suit gloves, respirator, face shield) required.

Environmental precautions: Avoid dispersal of spilled material, runoff and contact with soil, waterways, drains and sewers. Contain spill area.

Spill: Corrosive liquid! Ventilate area. Prevent runoff. Contain and collect spillage with absorbent material e.g. sand, earth, vermiculite etc and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Dilute

with water and mop-up or absorb with an inert dry material and place in an appropriate waste disposal container. Avoid contact with strong oxidizers.

7. HANDLING AND STORAGE

Handling: Avoid breathing vapors or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Store in ventilated areas.

Storage: Store in a well-ventilated, cool area for corrosive liquids. Keep container tightly closed and sealed until ready for use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits: For Concentrated Hydrochloric Acid

ACGIH TLV: TWA, 5 ppm, STEL1ppm
OSHA PEL: TWA: 5 ppm, STEL1ppm
NIOSH REL: TWA: 5 ppm ,STEL1ppm

Carcinogencity: NA

Engineering measures: Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne concentrations below any recommended threshold limits. Full safety shower should be in close proximity to working area.

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating and using the lavatory. Wash contaminated clothing before reusing.

Personal protection
Respiratory: If used in poorly ventilated areas, use a properly fitted, air-purifying or air-fed respirator complying with an approved standard. Respirator selection must be based on known or anticipated exposure levels.
Hands: Chemical-resistant neoprene gloves
Eyes: Safety eyewear; splash goggles, face shield
Skin: Lab coats for personal protective equipment and should be approved by a specialist before handling this product. Depending on volume/conditions a full acid suit may be necessary.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid.	**Color:**	Clear, slight yellow tint
Flash Point:	NA	**Odor:**	Pungent, strong, chlorine
pH:	~1	**Boiling/condensation point:**	NA
Melting/freezing point:	NA	**Relative density:**	~1.09
Vapor pressure:	160mm Hg@20°C	**Vapor density: Air=1**	1.267
Odor threshold:	NA	**Evaporation rate: BuAc=1**	2.0
VOC:	NA		
Solubility:	Soluble in the following materials: water		

10. STABILITY AND REACTIVITY

Chemical stability: The product is stable under normal conditions.
Possibility of hazardous reactions: Very Corrosive
Under normal conditions of storage and use, hazardous reactions will not occur.

Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid: Reaction with water is exothermic
Materials to avoid: Reactive or incompatible with: oxidizing materials, metals and alkaline materials
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not occur. Explosive hydrogen chloride/gas may form if decomposition occurs.

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50-Rabbit 900mg/kg

Inhalation LC50, Mouse 1hr - 1108ppm; Rat 1hr, 3124ppm

Other information on acute toxicity
no data available
Skin corrosion/irritation
Corrosive through skin absorption
Serious eye damage/eye irritation
Eyes: very corrosive
Respiratory or skin sensitization
Dryness, reddening, blistering
Germ cell mutagenicity
no data available
Specific target organ toxicity - single exposure (Globally Harmonized System)
Liver, respiratory/gastro tract, eyes and skin
Specific target organ toxicity - repeated exposure (Globally Harmonized System)
Liver, respiratory/gastro tract, eyes, skin and general overall organs
Aspiration hazard
Will burn mouth, throat and respiratory tract
Potential health effects
Inhalation May be toxic if inhaled. Causes respiratory tract inflammation/burns.
Ingestion May be toxic if swallowed and causes burns/tissue destruction.
Skin Toxic if absorbed through skin. Causes skin irritation/blisters.
Eyes Will burn eyes on contact.
Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Toxicity
LC50, fish 282mg/L 96 hr
Persistence and degradability
Expected to be biodegradable
Bioaccumulative potential
no data available
Mobility in soil
Product absorbs weakly to most soil types
PBT and vPvB assessment
no data available
Other adverse effects
no data available

13. DISPOSAL CONSIDERATIONS

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and

disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

DOT (US) UN 1789, Hydrochloric acid, 8, II

IMDG UN 2789, UN 1789, Hydrochloric acid, 8, II

IATA UN 2789, UN 1789, Hydrochloric acid, 8, II

15. REGULATORY INFORMATION

TSCA 8 (b): Listed on inventory
SARA 302/311/312/313/: Extremely hazardous material; RQ5000lbs, TPQ500lbs gas

OSHA Hazardous by definition (29CFR 1910.1200)

EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances

WHMIS (Canada): Class D-2A Material causing other toxic effects; Class E: Corrosive liquid

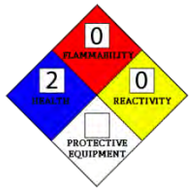
DEA List I Chemicals
Precursor Chemicals): Not listed
DEA List II Chemicals
Essential Chemicals):

RTK: Hydrochloric Acid Concentrated, CAS 7647-01-0, Listed, CA, CT, FL, MA, MN, NJ, PA, RI

California Prop 65 Components: No components listed for causing cancer, birth defects or any reproductive harm.

16. OTHER INFORMATION

National Fire Protection Association (U.S.A.)



Notice to reader
The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Healthlink shall not be liable for any damage resulting from handling of contact with this product.

SAFETY DATA SHEET

Revision Date 09-Jul-2015 **Version** 1

1. IDENTIFICATION

Product Name	Hydrochloric Acid Solution, 1.00 Normal
Product Code	5100
Recommended Use	For laboratory, scientific, R&D or manufacturing use.
Company	E K Industries, Inc. 1403 Herkimer St. Joliet, IL 60432 Tel. (800) 283-4244
Emergency Telephone	Call CHEMTREC 1-800-424-9300 (EKI CCN 7453)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Inhalation (Gases)	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1

Label elements

Signal word
Danger

Hazard statements
Harmful if inhaled. Causes skin irritation. Causes serious eye damage.

Precautionary Statements - Prevention
Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. Wash face, hands and any exposed skin thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or

doctor/physician if you feel unwell.

Precautionary Statements - Storage
Store in a well-ventilated place.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%
Water	7732-18-5	60 - 100
Hydrochloric acid	7647-01-0	3-5

4. FIRST AID MEASURES

Description of first aid measures

Eye contact Immediately flush with plenty of water for at least 15 minutes, separating eyelids occasionally. Remove contact lenses if present. Get immediate medical attention.

Skin contact Wash thoroughly with soap and water while removing contaminated garments. Get medical attention if irritation develops.

Inhalation Remove to fresh air. Get medical attention for any breathing difficulty.

Ingestion Do NOT induce vomiting. Rinse mouth. Drink 1 or 2 glasses of water. Never give anything by mouth to an unconscious person. Get medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms Causes skin and eye irritation.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Specific hazards arising from the chemical
No information available.

Protective equipment and precautions for firefighters
Firefighters should wear self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode.

NFPA **Health hazards** 2 **Flammability** 0 **Instability** 0 **Physical and Chemical Properties** -

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation, especially in confined areas.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Absorb spill with inert material, scoop up and containerize for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible materials Bases. Alkaline substances. Metals and metal oxides.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Hydrochloric acid 7647-01-0	Ceiling: 2 ppm	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m^3 Ceiling: 5 ppm Ceiling: 7 mg/m^3	IDLH: 50 ppm Ceiling: 5 ppm Ceiling: 7 mg/m^3

Appropriate engineering controls

Engineering Controls Emergency showers, eyewash stations, ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Tight sealing safety goggles.

Skin and body protection Wear protective gloves and protective clothing.

Respiratory protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear, colorless
Odor	Odor of hydrochloric acid
Odor threshold	No information available
pH	~1
Melting point / freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Relative density	No information available
Water solubility	Miscible with water
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available

Decomposition temperature No information available
Kinematic viscosity No information available

10. STABILITY AND REACTIVITY

Stability Stable under recommended storage conditions.

Possibility of Hazardous Reactions None under normal processing.

Conditions to avoid Extremes of temperature and direct sunlight

Incompatible materials Bases. Alkaline substances. Metals and metal oxides.

Hazardous Decomposition Products Hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation No data available.

Eye contact No data available.

Skin contact No data available.

Ingestion No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Hydrochloric acid 7647-01-0	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Information on toxicological effects

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.
Germ cell mutagenicity No information available.
Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen

Chemical Name	ACGIH	IARC	NTP	OSHA
Hydrochloric acid 7647-01-0	-	Group 3	-	-

IARC (International Agency for Research on Cancer)
Group 3 - Not classifiable as to carcinogenicity in humans

.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Hydrochloric acid 7647-01-0	-	282: 96 h Gambusia affinis mg/L LC50 static	-

Persistence and degradability
No information available.

Bioaccumulation
No information available.

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Emptied containers may contain residue. Continue to follow label warnings after container is emptied.

14. TRANSPORT INFORMATION

Transportation information is provided as a general reference only and may not be applicable in all situations. This information applies to non-bulk shipments only. Per 49 CRF 173.22, it is the shipper's responsibility to ensure that all materials are properly packaged, classified and labeled prior to shipment.

DOT

UN/ID no.	1789
Proper shipping name	Hydrochloric acid
Hazard Class	8
Packing Group	III

IATA

UN/ID no.	1789
Proper shipping name	Hydrochloric acid
Hazard Class	8
Packing Group	III

15. REGULATORY INFORMATION

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

Chemical Name	SARA 313 - Threshold Values %
Hydrochloric acid - 7647-01-0	1.0

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Hydrochloric acid 7647-01-0	5000 lb	-	-	X

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Hydrochloric acid 7647-01-0	5000 lb	5000 lb	RQ 5000 lb final RQ RQ 2270 kg final RQ

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Hydrochloric acid 7647-01-0	X	X	X

16. OTHER INFORMATION

Prepared By EKI Regulatory Affairs (Email: reg@eki-chem.com)
Revision Date 09-Jul-2015
Disclaimer
E K Industries, Inc. makes no representation as to the comprehensiveness or accuracy of this document. Individuals using this information, or the product to which it refers, must exercise their independent judgment in determining all appropriateness for a particular purpose. Accordingly, E K Industries, Inc. will not be responsible for damages of any kind or nature resulting from the use of this information or the corresponding product. No representations or warranties of any kind or nature, including but not limited to: express warranties, implied warranties or merchantability, or warranties of fitness for a particular purpose, are made hereunder with respect to the information set forth herein or to the product to which the information refers.

End of Safety Data Sheet

HealthLink® A Family of Medical Products
Joining Forces to Serve the Healthcare Community
CLOROX HEALTHCARE®

Safety Data Sheet

Hydrochloric Acid 10%

Revision Date: 6/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Hydrochloric Acid, 10%
Product code: 400501

Supplier: HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM

Synonym: None.
Material uses: Laboratory Reagent.
Validation date: 1/15/2015
In case of emergency: 800-424-9300 CHEMTREC (USA)
24 Hours/Day: 7 Days/Week

2. HAZARDS IDENTIFICATION

GHS Classification

Skin Corrosion (Category 1A), H314	H314 Cause severe skin and eye damage
Serious Eye Damage (Category 1), H318	H318 Causes serious eye damage

GHS Label Elements

Pictogram
Signal Word Danger!

Health Statement(s):
H318: Causes serious eye damage (Cat 1)
H314: Causes severe skin burns and eye damage (Cat 1)
H370: Causes damage to organs (Cat 1)
H305: May be harmful if swallowed and enters airways (Cat 2)

Precautionary statement(s):
P280: Wear protective gloves/ eye protection/ face protection.
P305+351+338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Potential Acute Health Effects:
Very hazardous in case of contact with eye, skin, ingestion and inhalation. Liquid or spray mist may produce tissue damage especially mucous membranes of eyes, mouth and respiratory tract. Will burn eyes and skin on contact. Respiratory track characterized by coughing, choking and shortness of breath. Inflammation of eyes results in redness, watering and itching. Skin contact results in scaling, redness or blistering.

Potential Chronic Helath Effects:
Carcinogenic Effects, NA; Mutagenic Effects, NA; Teratogenic Effects, NA; Developmental Toxicity, NA. May be toxic to kidneys, liver, mucous membranes, repiratory tract, skin and teeth.

Target Organs
Respiratory Tract

NFPA Rating	**HMIS Classification**
Health hazard: 3	Health hazard: 3
Fire: 0	Flammability: 0
Reactivity Hazard: 1	Physical hazards: 1

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	**CAS number**	**% by volume**
Hydrochloric Acid	7647-01-0	~ 10
Water	7732-18-5	~ 90

4. FIRST AID MEASURES

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with water for 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention immediately.

Skin contact: Flush skin with water for 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.

Inhalation: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.

Ingestion: Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

5. FIRE-FIGHTING MEASURES

Flammability of the product: Non-**F**lammable

Extinguishing media: Use suitable media for surrounding materials. If water use fog spray, avoid direct stream.

Special exposure hazards: Avoid contact with metal, hydrogen chloride gas can react with aluminum, tin, lead, zinc

Decomposition products: Decomposition products: hydrogen gas, hydrogen chloride gas

Special protective equipment for fire-fighters: Use self-contained breathing apparatus with water spray.

Explosion hazards: hydrogen gas can form in fire situation which is flammable.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary and unprotected personnel from entering area. Avoid breathing vapors. Provide adequate ventilation. Do not touch or walk through spilled material. Beware of vapors accumulating to form explosive hydrogen gas mixtures. Full personal safety equipment (suit gloves, respirator, face shield) required.

Environmental precautions: Avoid dispersal of spilled material, runoff and contact with soil, waterways, drains and sewers. Contain spill area.

Spill: Corrosive liquid! Ventilate area. Prevent runoff. Contain and collect spillage with absorbent material e.g. sand, earth, vermiculite etc and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Dilute

with water and mop-up or absorb with an inert dry material and place in an appropriate waste disposal container. Avoid contact with strong oxidizers.

7. HANDLING AND STORAGE

Handling: Avoid breathing vapors or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Store in ventilated areas.

Storage: Store in a well-ventilated, cool area for corrosive liquids. Keep container tightly closed and sealed until ready for use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits: For Concentrated Hydrochloric Acid

ACGIH TLV: TWA, 5 ppm, STEL1ppm
OSHA PEL: TWA: 5 ppm, STEL1ppm
NIOSH REL: TWA: 5 ppm ,STEL1ppm

Carcinogencity: NA

Engineering measures: Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne concentrations below any recommended threshold limits. Full safety shower should be in close proximity to working area.

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating and using the lavatory. Wash contaminated clothing before reusing.

Personal protection
Respiratory: If used in poorly ventilated areas, use a properly fitted, air-purifying or air-fed respirator complying with an approved standard. Respirator selection must be based on known or anticipated exposure levels.
Hands: Chemical-resistant neoprene gloves
Eyes: Safety eyewear; splash goggles, face shield
Skin: Lab coats for personal protective equipment and should be approved by a specialist before handling this product. Depending on volume/conditions a full acid suit may be necessary.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid.	**Color:**	Clear, slight yellow tint
Flash Point:	NA	**Odor:**	Pungent, strong, chlorine
pH:	~1	**Boiling/condensation point:**	NA
Melting/freezing point:	NA	**Relative density:**	~1.09
Vapor pressure:	160mm Hg@20°C	**Vapor density: Air=1**	1.267
Odor threshold:	NA	**Evaporation rate: BuAc=1**	2.0
VOC:	NA		
Solubility:	Soluble in the following materials: water		

10. STABILITY AND REACTIVITY

Chemical stability: The product is stable under normal conditions.
Possibility of hazardous reactions: Very Corrosive
Under normal conditions of storage and use, hazardous reactions will not occur.

Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid: Reaction with water is exothermic
Materials to avoid: Reactive or incompatible with: oxidizing materials, metals and alkaline materials
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not occur. Explosive hydrogen chloride/gas may form if decomposition occurs.

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50-Rabbit 900mg/kg

Inhalation LC50, Mouse 1hr - 1108ppm; Rat 1hr, 3124ppm

Other information on acute toxicity
no data available
Skin corrosion/irritation
Corrosive through skin absorption
Serious eye damage/eye irritation
Eyes: very corrosive
Respiratory or skin sensitization
Dryness, reddening, blistering
Germ cell mutagenicity
no data available
Specific target organ toxicity - single exposure (Globally Harmonized System)
Liver, respiratory/gastro tract, eyes and skin
Specific target organ toxicity - repeated exposure (Globally Harmonized System)
Liver, respiratory/gastro tract, eyes, skin and general overall organs
Aspiration hazard
Will burn mouth, throat and respiratory tract
Potential health effects
Inhalation May be toxic if inhaled. Causes respiratory tract inflammation/burns.
Ingestion May be toxic if swallowed and causes burns/tissue destruction.
Skin Toxic if absorbed through skin. Causes skin irritation/blisters.
Eyes Will burn eyes on contact.
Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Toxicity
LC50, fish 282mg/L 96 hr
Persistence and degradability
Expected to be biodegradable
Bioaccumulative potential
no data available
Mobility in soil
Product absorbs weakly to most soil types
PBT and vPvB assessment
no data available
Other adverse effects
no data available

13. DISPOSAL CONSIDERATIONS

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and

disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

DOT (US) UN 1789, Hydrochloric acid, 8, II

IMDG UN 2789, UN 1789, Hydrochloric acid, 8, II

IATA UN 2789, UN 1789, Hydrochloric acid, 8, II

15. REGULATORY INFORMATION

TSCA 8 (b): Listed on inventory
SARA 302/311/312/313/: Extremely hazardous material; RQ5000lbs, TPQ500lbs gas

OSHA Hazardous by definition (29CFR 1910.1200)

EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances

WHMIS (Canada): Class D-2A Material causing other toxic effects; Class E: Corrosive liquid

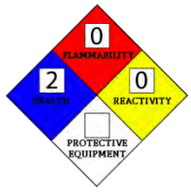
DEA List I Chemicals
Precursor Chemicals): Not listed
DEA List II Chemicals
Essential Chemicals):

RTK: Hydrochloric Acid Concentrated, CAS 7647-01-0, Listed, CA, CT, FL, MA, MN, NJ, PA, RI

California Prop 65 Components: No components listed for causing cancer, birth defects or any reproductive harm.

16. OTHER INFORMATION

National Fire Protection Association (U.S.A.)



Notice to reader
The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Healthlink shall not be liable for any damage resulting from handling of contact with this product.

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	Influenza A & B Test, Dipstick

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use(s)	*In vitro* diagnostic reagent. For professional use only.

1.3 Details of the supplier of the safety data sheet

Company Identification	Alere Scarborough Inc., 10 Southgate Road, Scarborough, Maine 04074, USA.
Telephone	+1 207-730-5750
E-Mail (competent person)	ts.scr@alere.com

1.4 Emergency telephone number

Emergency Phone No.	+1 207-730-5750

►SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS

Not classified as hazardous.

2.2 Label elements

Not applicable.

2.3 Other hazards

None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Description:	*In vitro* diagnostic reagent. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.
Dangerous components:	The product does not contain reportable quantities of dangerous components.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information	The following first aid measures are not expected to be required unless there is severe misuse of the product
Inhalation	Supply fresh air; consult doctor in case of complaint.
Skin Contact	Wash skin with soap and water.
Eye Contact	Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion	Wash out mouth with water. Consult a doctor.

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4.2	**Most important symptoms and effects, both acute and delayed**	None.
4.3	**Indication of the immediate medical attention and special treatment needed**	None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1	**Extinguishing media**	
	Suitable Extinguishing Media	CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
5.2	**Special hazards arising from the substance or mixture**	In case of fire, the following can be released: Carbon oxides (COx), nitrogen oxides (NOx),
5.3	**Advice for fire-fighters**	Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	**Personal precautions, protective equipment and emergency procedures**	Refer to Section 8 for protective measures when handling the spillage.
6.2	**Environmental precautions**	No special requirements.
6.3	**Methods and material for containment and cleaning up**	Collect material and dispose of as waste according to Section 13.
6.4	**Reference to other sections**	8, 13

SECTION 7: HANDLING AND STORAGE

7.1	**Precautions for safe handling**	Specimens should be handled as potentially infectious materials. Refer to Regulation 29 CFR 1910.1030 for information on handling biohazardous materials. Avoid contact with skin and eyes. Keep out of reach of children. Wash hands and exposed skin after use. Clean work areas with hypochlorite or other disinfecting agent.
7.2	**Conditions for safe storage, including any incompatibilities**	Store in the original container at 4 to 30°C.
7.3	**Specific end use(s)**	Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	**Control parameters**	
8.1.1	**Occupational Exposure Limits**	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
8.2	**Exposure controls**	
8.2.1	**Appropriate engineering controls**	Not relevant for this material.
8.2.2	**Personal protection equipment**	
	Eye/face protection	Not normally required.
	Hand protection (Hygiene Measures)	Disposable gloves.

Material of gloves:	Latex / natural rubber, Nitrile rubber.
Penetration time of glove material:	Gloves resistance is not critical when the product is handled according to the instructions for use.
Body protection	
Respiratory protection	Laboratory coat.

8.2.3 Environmental Exposure Controls No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.
Color	White.
Odor	No odor.
Odor Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not available.
Boiling point/boiling range (°C):	Not applicable.
Flash Point (°C)	Not applicable
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapor Pressure (Pascal)	Not applicable.
Vapor Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Not applicable.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

9.2 Other information Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity None known.

10.2 Chemical stability The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerization will not occur.

10.4 Conditions to avoid None.

10.5 Incompatible materials Strong Acids.

10.6 Hazardous Decomposition Product(s) None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitization	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2	**Persistence and degradability**	The product is likely to persist in the environment.
12.3	**Bioaccumulative potential**	The product has low potential for bioaccumulation.
12.4	**Mobility in soil**	No data.
12.5	**Results of PBT and vPvB assessment**	Not applicable
12.6	**Other adverse effects**	Not applicable

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Packaging:	Disposal should be in accordance with applicable federal, state and local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service

providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	**UN number**	Not applicable
14.2	**Proper Shipping Name**	Not applicable
14.3	**Transport hazard class(es)**	Not classified as dangerous for transport.
14.4	**Packing Group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special precautions for user**	Not applicable
14.7	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	**Safety, health and environmental regulations/legislation specific for the substance or mixture**	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Chemical inventory listings relevant to US regulations	
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	Sodium azide (< 1.0%)
	Section 313 (specific toxic chemical listings):	Sodium azide (< 0.1%)
15.2	**Chemical Safety Assessment**	Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Additional Information

Reason for update:	Update in accordance with GHS. Changes to section 2 ► Indicates altered section
Supersedes:	Version: 1

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present

unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Kit SDS Cover Sheet

Document ID: OSR6122-75: Version 06
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/01/10

Product Information

Product Name	Inorganic Phosphorous
Part Number	OSR6122, OSR6222

Components

Description

Inorganic Phosphorous R1
Inorganic Phosphorous R2

Transport Information

Shipping Information	**IATA**	**IMDG**	**US DOT**	**European ADR**	**Canadian TDG**
UN/ID Number	2796	2796	2796	2796	2796
Shipping Name	Sulfuric acid solution				
Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
Subsidiary Risk	None	None	None	None	None
Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
Packing Group	II	II	II	II	II
Special Provisions	None	None	A3, A7, N34	None	None
Additional information					
IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	157	Not applicable	157
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

Warning: Corrosive substances.

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SAFETY DATA SHEET

Document ID: OSR6122-75 Version 06
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/01/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Inorganic Phosphorous R1

Part Number Component of P/N OSR6122, OSR6222

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sulfuric Acid
Polyoxyethylated Octyl Phenol

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sulfuric Acid CAS # 7664-93-9 EINECS # 231-639-5 Index # 016-020-00-8	5 - 10	Eye Dam. 1, H318 Skin Corr. 1A, H314	Eye Dam. 1, H318 Skin Corr. 1A, H314	

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Section 3 Composition and Information on Ingredients (Continued)

Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # 618-344-0 Index # Not available	0.5 - 1	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	SVHC

SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sulfuric Acid
CAS # 7664-93-9 1 mg/m3 TWA

ACGIH

Sulfuric Acid
CAS # 7664-93-9 0.2 mg/m3 TWA (thoracic particulate matter)

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Sulfuric Acid CAS # 7664-93-9	0.1 mg/m3 Peak (inhalable fraction); 0.1 mg/m3 TWA MAK

Ireland

Sulfuric Acid CAS # 7664-93-9	0.05 ppm TWA; 0.15 ppm STEL (calculated)

IOELVs

Sulfuric Acid CAS # 7664-93-9	0.05 mg/m3 TWA

NIOSH

Sulfuric Acid CAS # 7664-93-9	15 mg/m3 IDLH; 1 mg/m3 TWA

Japan None established

Sweden (AFS 2015:7 and amendments)

Sulfuric Acid CAS # 7664-93-9	0.1 mg/m3 TLV; 0.2 mg/m3 Indicative STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.07
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	< 1	**Partition n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Sulfuric Acid 0.15 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
Sulfuric Acid CAS # 7664-93-9	Inhalation LC50 Rat 85 - 103 mg/m3 1 h; Oral LD50 Rat 2140 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Contact may cause severe skin burns.
Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	Sulfuric Acid is listed with OSHA as a carcinogen; IARC as Group 1 carcinogen to humans; ACGIH as A2 Suspected Human Carcinogen.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sulfuric Acid CAS # 7664-93-9	96 h LC50 Brachydanio rerio: >500 mg/L [static]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	2796	2796	2796	2796	PIN - 2796
14.2	Shipping Name	Sulfuric acid solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
14.4	Packing Group	II	II	II	II	II
	Special Provisions	None	None	A3, A7, N34	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	157	Not applicable	157

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Section 14 Transport Information (Continued)

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 7664-93-9 Sulfuric Acid 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7664-93-9 Sulfuric Acid

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 7664-93-9 Sulfuric Acid

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7664-93-9 Sulfuric Acid

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7664-93-9 Sulfuric Acid

Pennsylvania Right To Know (RTK) List

CAS # 7664-93-9 Sulfuric Acid

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated E-mail address in Sec. 1.3.
Updated Section 4, 8, 11, 12, 15
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/01/10
Document ID: OSR6122-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
Skin Corr. 1A - Skin Corrosion Category 1A
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.
H411 - Toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Document ID: OSR6122-75 Version 06
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/01/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Inorganic Phosphorous R2

Part Number Component of P/N OSR6122, OSR6222

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sulfuric Acid
Polyoxyethylated Octyl Phenol

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sulfuric Acid CAS # 7664-93-9 EINECS # 231-639-5 Index # 016-020-00-8	5 - 10	Eye Dam. 1, H318 Skin Corr. 1A, H314	Eye Dam. 1, H318 Skin Corr. 1A, H314	

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Section 3 Composition and Information on Ingredients (Continued)

Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # 618-344-0 Index # Not available	0.5 - 1	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	SVHC

SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sulfuric Acid
CAS # 7664-93-9 1 mg/m3 TWA

ACGIH

Sulfuric Acid
CAS # 7664-93-9 0.2 mg/m3 TWA (thoracic particulate matter)

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Sulfuric Acid CAS # 7664-93-9	0.1 mg/m3 Peak (inhalable fraction); 0.1 mg/m3 TWA MAK

Ireland

Sulfuric Acid CAS # 7664-93-9	0.05 ppm TWA; 0.15 ppm STEL (calculated)

IOELVs

Sulfuric Acid CAS # 7664-93-9	0.05 mg/m3 TWA

NIOSH

Sulfuric Acid CAS # 7664-93-9	15 mg/m3 IDLH; 1 mg/m3 TWA

Japan None established

Sweden (AFS 2015:7 and amendments)

Sulfuric Acid CAS # 7664-93-9	0.1 mg/m3 TLV; 0.2 mg/m3 Indicative STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.07
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	< 1	**Partition n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Sulfuric Acid 0.15 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
Sulfuric Acid CAS # 7664-93-9	Inhalation LC50 Rat 85 - 103 mg/m3 1 h; Oral LD50 Rat 2140 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Contact may cause severe skin burns.
Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	Sulfuric Acid is listed with OSHA as a carcinogen; IARC as Group 1 carcinogen to humans; ACGIH as A2 Suspected Human Carcinogen.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sulfuric Acid CAS # 7664-93-9	96 h LC50 Brachydanio rerio: >500 mg/L [static]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Inorganic Phosphorous
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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	2796	2796	2796	2796	PIN - 2796
14.2	Shipping Name	Sulfuric acid solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
14.4	Packing Group	II	II	II	II	II
	Special Provisions	None	None	A3, A7, N34	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	157	Not applicable	157

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Section 14 Transport Information (Continued)

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 7664-93-9	Sulfuric Acid	1.0% de minimis concentration
CAS # 12054-85-2	Ammonium Para-Molybdate Tetrahydrate	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7664-93-9	Sulfuric Acid

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 7664-93-9	Sulfuric Acid

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7664-93-9	Sulfuric Acid

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7664-93-9	Sulfuric Acid

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 7664-93-9 Sulfuric Acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated E-mail address in Sec. 1.3.
Updated Section 4, 8, 11, 12, 15
Updated Section 16.

Document version and issue/revision date

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Description of hazard Class and hazard statements from Section 3

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
Skin Corr. 1A - Skin Corrosion Category 1A
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.
H411 - Toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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ISE Internal Reference Solution

SAFETY DATA SHEET

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Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name ISE Internal Reference Solution

Part Number AUH1017

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

This safety data sheet is provided for information only, not required by regulations

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

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Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

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Section 6 Accidental Release Measures (Continued)

6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	No special precautions are necessary; use good laboratory procedures.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 15 to 25°C , as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	None established
	DFG MAK	None established
	Ireland	None established
	IOELVs	None established
	NIOSH	None established
	Japan	None established
	Sweden (AFS 2015:7 and amendments)	
		None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.24389 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	Not determined	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

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ISE Internal Reference Solution

Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

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Section 15 Regulatory Information (Continued)

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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BECKMAN COULTER
ISE Internal Reference Solution

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 4, 8, 11, 13 - 16.

Updated Section 1.

Document version and issue/revision date

Revision Date (year/month/day) 2019/07/03

Last Revision Date (year/month/day) 2015/03/20

Document ID: AUH1017-75
Version: 04

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6186-75: Version 05
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/04/02

Product Information

Product Name	**Iron**
Part Number	OSR6186, OSR6286

Components

Description	Iron R1 Iron R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6186-75 Version 05
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/04/02

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Iron R1

Part Number Component of P/N OSR6186, OSR6286

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless to slightly yellow; Not available; Liquid; Mild

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Poly(oxy-1,2-ethanediyl), .alpha.-[3,5-dimethyl-1-(2-methylpropyl)hexyl]-.omega.-hydroxy-

Hydrochloric Acid

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Poly(oxy-1,2-ethanediyl), .alpha.-[3,5-dimethyl-1-(2-methylpropyl)hexyl]-.omega.-hydroxy- CAS # 60828-78-6 EINECS # Not available Index # Not available	1 - 2	Eye Dam. 1, H318	Acute Tox. Dermal 5, H313 Eye Dam. 1, H318 Skin Irrit. 3, H316	
Hydrochloric Acid CAS # 7647-01-0 EINECS # 231-595-7 Index # 017-002-01-X	< 0.1	Acute Tox. Oral 4, H302 STOT SE 3, H335 Skin Corr. 1B, H314	Acute Tox. Oral 4, H302 STOT SE 3, H335 Skin Corr. 1B, H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Hydrochloric Acid CAS # 7647-01-0	5 ppm Ceiling; 7 mg/m3 Ceiling

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Hydrochloric Acid CAS # 7647-01-0	2 ppm Ceiling

DFG MAK

Hydrochloric Acid CAS # 7647-01-0	4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

Ireland

Hydrochloric Acid CAS # 7647-01-0	5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

IOELVs

Hydrochloric Acid CAS # 7647-01-0	10 ppm STEL; 15 mg/m3 STEL; 5 ppm TWA; 8 mg/m3 TWA

NIOSH

Hydrochloric Acid CAS # 7647-01-0	50 ppm IDLH

Japan None established

Sweden (AFS 2015:7 and amendments)

Hydrochloric Acid CAS # 7647-01-0	2 ppm TLV; 3 mg/m3 TLV; 4 ppm Binding STEL; 6 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Colorless to slightly yellow	**Solubility**	
Transparency	Not available	**Water**	Fully miscible
Odor	Mild	**Organic**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

pH	1.7	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	None determined
Flammability Limits	Not determined	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Hydrochloric Acid 0.06 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Poly(oxy-1,2-ethanediyl), .alpha.-[3,5-dimethyl-1-(2-methylpropyl)hexyl]-.omega.-hydroxy- CAS # 60828-78-6	Dermal LD50 Rabbit 4780 µL/kg; Oral LD50 Rat 5650 mg/kg
Hydrochloric Acid CAS # 7647-01-0	Dermal LD50 Rabbit >5010 mg/kg; Inhalation LC50 Rat 1.68 mg/L 1 h; Oral LD50 Rat 238 - 277 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Contact may cause severe skin burns.

Serious eye damage/eye irritation Contact may cause serious eye damage.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.
Microtox No information available.
Water Flea No information available.
Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

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Section 12 Ecological Information (Continued)

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 7647-01-0	Hydrochloric Acid	1.0% de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7647-01-0 Hydrochloric Acid

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

Pennsylvania Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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BECKMAN COULTER

Iron
Iron R1

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 3, 4, 6 - 8, 11, 12, 14 - 16.

Updated Section 9.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/11

Last Revision Date (year/month/day) 2015/04/02

Document ID: OSR6186-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4

Eye Dam. 1 - Eye Damage Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Irrit. 3 - Skin Irritation Category 3

STOT SE 3 - Target Organ Toxicity Single Exposure Category 3

H302 - Harmful if swallowed.

H313 - May be harmful in contact with skin

H314 - Causes severe skin burns and eye damage.

H316 - Causes mild skin irritation.

H318 - Causes serious eye damage.

H335 - May cause respiratory irritation.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA DGR - International Air Transport Association Dangerous Goods Regulation

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

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Section 16 Other Information (Continued)

OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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SAFETY DATA SHEET

Document ID: OSR6186-75 Version 05
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/04/02

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Iron R2

Part Number Component of P/N OSR6186, OSR6286

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless to slightly yellow; Not available; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Hydrochloric Acid

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Hydrochloric Acid CAS # 7647-01-0 EINECS # 231-595-7 Index # 017-002-01-X	< 0.1	Acute Tox. Oral 4, H302 STOT SE 3, H335 Skin Corr. 1B, H314	Acute Tox. Oral 4, H302 STOT SE 3, H335 Skin Corr. 1B, H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Hydrochloric Acid CAS # 7647-01-0	5 ppm Ceiling; 7 mg/m3 Ceiling

ACGIH

Hydrochloric Acid CAS # 7647-01-0	2 ppm Ceiling

DFG MAK

Hydrochloric Acid CAS # 7647-01-0	4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

Ireland

Hydrochloric Acid CAS # 7647-01-0	5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

IOELVs

Hydrochloric Acid CAS # 7647-01-0	10 ppm STEL; 15 mg/m3 STEL; 5 ppm TWA; 8 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

NIOSH

Hydrochloric Acid CAS # 7647-01-0	50 ppm IDLH

Japan None established

Sweden (AFS 2015:7 and amendments)

Hydrochloric Acid CAS # 7647-01-0	2 ppm TLV; 3 mg/m3 TLV; 4 ppm Binding STEL; 6 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Colorless to slightly yellow	**Solubility**	
Transparency	Not available	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	1.7	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	None determined

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Section 9 Physical and Chemical Properties (Continued)

	Flammability Limits	Not determined	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Hydrochloric Acid 0.06 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Hydrochloric Acid CAS # 7647-01-0	Dermal LD50 Rabbit >5010 mg/kg; Inhalation LC50 Rat 1.68 mg/L 1 h; Oral LD50 Rat 238 - 277 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Contact may cause severe skin burns.
Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 7647-01-0	Hydrochloric Acid	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7647-01-0	Hydrochloric Acid

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7647-01-0	Hydrochloric Acid

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

Pennsylvania Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated Section 3, 4, 6 - 8, 11, 12, 14 - 16.
Updated Section 9.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/04/02
Document ID: OSR6186-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Skin Corr. 1B - Skin Corrosion Category 1B
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H335 - May cause respiratory irritation.

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Iron
Iron R2

SAFETY DATA SHEET

Document ID: OSR6186-75 Version 05
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/04/02

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: AUH1018-75: Version 04
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20

Product Information

Product Name	ISE (K+) and (Na+) SELECTIVITY CHECK SOLUTION
Part Number	AUH1018

Components

Description	ISE (K+) SELECTIVITY CHECK SOLUTION ISE (NA+) SELECTIVITY CHECK SOLUTION

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: AUH1018-75 Version 04
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name ISE (K+) SELECTIVITY CHECK SOLUTION

Part Number Component of P/N AUH1018

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

Formaldehyde

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	< 0.1	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	15, 8

15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

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Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Formaldehyde CAS # 50-00-0	0.75 ppm TWA; 2 ppm STEL (see 29 CFR 1910.1048)

ACGIH

Formaldehyde CAS # 50-00-0	0.3 ppm STEL; 0.1 ppm TWA

DFG MAK

Formaldehyde CAS # 50-00-0	0.6 ppm Peak (no irritation should occur during mixed exposure); 0.74 mg/m3 Peak (no irritation should occur during mixed exposure); 0.3 ppm TWA MAK; 0.37 mg/m3 TWA MAK (no irritation should occur during mixed exposure)

Ireland

Formaldehyde CAS # 50-00-0	0.2 ppm TWA; 0.4 ppm STEL

IOELVs None established

NIOSH

Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA

Japan

Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Formaldehyde CAS # 50-00-0	0.3 ppm TLV; 0.37 mg/m3 TLV; 0.6 ppm Binding STEL; 0.74 mg/m3 Binding STEL; Skin notation

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.9	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formaldehyde 0.027 ppm odor threshold value (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Formaldehyde CAS # 50-00-0	Dermal LD50 Rabbit 270 mg/kg; Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 100 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Formaldehyde CAS # 50-00-0	96 h LC50 Pimephales promelas: 22.6 - 25.7 mg/L -through]; 96 h LC50 Lepomis macrochirus: 1510 µg/L [static]; 96 h LC50 Brachydanio rerio: 41 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 0.032 - 0.226 mL/L -through]; 96 h LC50 Oncorhynchus mykiss: 100 - 136 mg/L [static]; 96 h LC50 Pimephales promelas: 23.2 - 29.7 mg/L [static]
Microtox	No information available.

Water Flea

Formaldehyde CAS # 50-00-0	48 h LC50 Daphnia magna: 2 mg/L; 48 h EC50 Daphnia magna: 11.3 - 18 mg/L [Static]
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 50-00-0	Formaldehyde	0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 50-00-0	Formaldehyde

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 50-00-0	Formaldehyde

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 50-00-0	Formaldehyde

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ISE (K+) SELECTIVITY CHECK SOLUTION

Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 50-00-0 Formaldehyde

Pennsylvania Right To Know (RTK) List

CAS # 50-00-0 Formaldehyde

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 4, 8, 9, 11 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20
Document ID: AUH1018-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.

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ISE (K+) and (Na+) SELECTIVITY CHECK SOLUTION
ISE (K+) SELECTIVITY CHECK SOLUTION

Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Document ID: AUH1018-75 Version 04
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name ISE (NA+) SELECTIVITY CHECK SOLUTION

Part Number Component of P/N AUH1018

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

Formaldehyde

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	< 0.1	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	15, 8

15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

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ISE (NA+) SELECTIVITY CHECK SOLUTION

SAFETY DATA SHEET
Document ID: AUH1018-75 Version 04
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20

Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Formaldehyde CAS # 50-00-0	0.75 ppm TWA; 2 ppm STEL (see 29 CFR 1910.1048)

ACGIH

Formaldehyde CAS # 50-00-0	0.3 ppm STEL; 0.1 ppm TWA

DFG MAK

Formaldehyde CAS # 50-00-0	0.6 ppm Peak (no irritation should occur during mixed exposure); 0.74 mg/m3 Peak (no irritation should occur during mixed exposure); 0.3 ppm TWA MAK; 0.37 mg/m3 TWA MAK (no irritation should occur during mixed exposure)

Ireland

Formaldehyde CAS # 50-00-0	0.2 ppm TWA; 0.4 ppm STEL

IOELVs None established

NIOSH

Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA

Japan

Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Formaldehyde CAS # 50-00-0	0.3 ppm TLV; 0.37 mg/m3 TLV; 0.6 ppm Binding STEL; 0.74 mg/m3 Binding STEL; Skin notation

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.9	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formaldehyde 0.027 ppm odor threshold value (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Formaldehyde CAS # 50-00-0	Dermal LD50 Rabbit 270 mg/kg; Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 100 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Formaldehyde CAS # 50-00-0	96 h LC50 Pimephales promelas: 22.6 - 25.7 mg/L -through]; 96 h LC50 Lepomis macrochirus: 1510 µg/L [static]; 96 h LC50 Brachydanio rerio: 41 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 0.032 - 0.226 mL/L -through]; 96 h LC50 Oncorhynchus mykiss: 100 - 136 mg/L [static]; 96 h LC50 Pimephales promelas: 23.2 - 29.7 mg/L [static]
Microtox	No information available.

Water Flea

Formaldehyde CAS # 50-00-0	48 h LC50 Daphnia magna: 2 mg/L; 48 h EC50 Daphnia magna: 11.3 - 18 mg/L [Static]
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 50-00-0	Formaldehyde	0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 50-00-0	Formaldehyde

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 50-00-0	Formaldehyde

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 50-00-0	Formaldehyde

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 50-00-0 Formaldehyde

Pennsylvania Right To Know (RTK) List

CAS # 50-00-0 Formaldehyde

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 4, 8, 9, 11 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20
Document ID: AUH1018-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.

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ISE (NA+) SELECTIVITY CHECK SOLUTION

Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER
ISE High Serum Standard

SAFETY DATA SHEET

Document ID: AUH1015-75 Version 04
Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name ISE High Serum Standard

Part Number AUH1015

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 CLP/GHS**

Hazardous Ingredients

Formaldehyde

Pictogram

None

Signal Word

None

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ISE High Serum Standard

SAFETY DATA SHEET

Document ID: AUH1015-75 Version 04
Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 2 Hazards (Continued)

2.3 Other hazards

Hazard Statements

EUH208 May produce an allergic reaction.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	< 0.1	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	15, 8

15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

Formaldehyde CAS # 50-00-0	0.75 ppm TWA; 2 ppm STEL (see 29 CFR 1910.1048)

ACGIH

Formaldehyde CAS # 50-00-0	0.3 ppm STEL; 0.1 ppm TWA

DFG MAK

Formaldehyde CAS # 50-00-0	0.6 ppm Peak (no irritation should occur during mixed exposure); 0.74 mg/m3 Peak (no irritation should occur during mixed exposure); 0.3 ppm TWA MAK; 0.37 mg/m3 TWA MAK (no irritation should occur during mixed exposure)

Ireland

Formaldehyde CAS # 50-00-0	0.2 ppm TWA; 0.4 ppm STEL

IOELVs None established

NIOSH

Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA

Japan

Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Formaldehyde CAS # 50-00-0	0.3 ppm TLV; 0.37 mg/m3 TLV; 0.6 ppm Binding STEL; 0.74 mg/m3 Binding STEL; Skin notation

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

pH	8 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formaldehyde 0.027 ppm odor threshold value (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Formaldehyde CAS # 50-00-0	Dermal LD50 Rabbit 270 mg/kg; Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 100 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.	
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Formaldehyde CAS # 50-00-0	96 h LC50 Pimephales promelas: 22.6 - 25.7 mg/L -through]; 96 h LC50 Lepomis macrochirus: 1510 µg/L [static]; 96 h LC50 Brachydanio rerio: 41 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 0.032 - 0.226 mL/L -through]; 96 h LC50 Oncorhynchus mykiss: 100 - 136 mg/L [static]; 96 h LC50 Pimephales promelas: 23.2 - 29.7 mg/L [static]
Microtox	No information available.

Water Flea

Formaldehyde CAS # 50-00-0	48 h LC50 Daphnia magna: 2 mg/L; 48 h EC50 Daphnia magna: 11.3 - 18 mg/L [Static]
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 50-00-0	Formaldehyde	0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 50-00-0	Formaldehyde

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Section 15 Regulatory Information (Continued)

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 50-00-0 Formaldehyde

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7757-82-6 Sodium Sulfate
CAS # 50-00-0 Formaldehyde

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 50-00-0 Formaldehyde

Pennsylvania Right To Know (RTK) List

CAS # 7757-82-6 Sodium Sulfate
CAS # 50-00-0 Formaldehyde

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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SAFETY DATA SHEET

Document ID: AUH1015-75 Version 04
Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 4, 8, 9, 11 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20
Document ID: AUH1015-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values

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SAFETY DATA SHEET

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Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information (Continued)

NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Document ID: AUH1012-75 Version 04
Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name ISE Mid Standard Solution

Part Number AUH1012

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.
Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Carcinogenicity Category 1

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Skin Sensitization Category 1
Carcinogenicity Category 1

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Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Triethanolamine

Formaldehyde

Pictogram

Signal Word

DANGER

Hazard Statements

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H350 May cause cancer.

Precautionary Statements

P201 Obtain special instructions before use.
P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Triethanolamine CAS # 102-71-6 EINECS # 203-049-8 Index # Not available	1 - 2	Eye Irrit. 2, H319 Skin Irrit. 2, H315	Eye Irrit. 2, H319 Skin Irrit. 2, H315	

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Document ID: AUH1012-75 Version 04
Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 3 Composition and Information on Ingredients (Continued)

Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	0.2 - 0.5	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	
Phosphoric Acid CAS # 7664-38-2 EINECS # 231-633-2 Index # 015-011-00-6	< 1	Acute Tox. Inhal. 2, H330 Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Corr. 1B, H314	Acute Tox. Inhal. 2, H330 Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Corr. 1B, H314	3, 8

3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause cancer.
May cause an allergic skin reaction.
Causes mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Phosphoric Acid CAS # 7664-38-2	1 mg/m3 TWA
Formaldehyde CAS # 50-00-0	0.75 ppm TWA; 2 ppm STEL (see 29 CFR 1910.1048)

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Phosphoric Acid CAS # 7664-38-2	3 mg/m3 STEL; 1 mg/m3 TWA
Formaldehyde CAS # 50-00-0	0.3 ppm STEL; 0.1 ppm TWA
Triethanolamine CAS # 102-71-6	5 mg/m3 TWA

DFG MAK

Phosphoric Acid CAS # 7664-38-2	4 mg/m3 Peak (inhalable fraction); 2 mg/m3 TWA MAK (inhalable fraction)
Formaldehyde CAS # 50-00-0	0.6 ppm Peak (no irritation should occur during mixed exposure); 0.74 mg/m3 Peak (no irritation should occur during mixed exposure); 0.3 ppm TWA MAK; 0.37 mg/m3 TWA MAK (no irritation should occur during mixed exposure)
Triethanolamine CAS # 102-71-6	1 mg/m3 Peak (inhalable fraction); 1 mg/m3 TWA MAK (can occur as vapor and aerosol at the same time) (inhalable fraction)

Ireland

Phosphoric Acid CAS # 7664-38-2	1 mg/m3 TWA; 2 mg/m3 STEL (as Os)
Formaldehyde CAS # 50-00-0	0.2 ppm TWA; 0.4 ppm STEL
Triethanolamine CAS # 102-71-6	5 mg/m3 TWA; 15 mg/m3 STEL (calculated)

IOELVs

Phosphoric Acid CAS # 7664-38-2	2 mg/m3 STEL; 1 mg/m3 TWA

NIOSH

Phosphoric Acid CAS # 7664-38-2	1000 mg/m3 IDLH; 3 mg/m3 STEL; 1 mg/m3 TWA
Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA

Japan

Phosphoric Acid CAS # 7664-38-2	1 mg/m3 OEL
Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Phosphoric Acid CAS # 7664-38-2	1 mg/m3 TLV; 2 mg/m3 Binding STEL
Formaldehyde CAS # 50-00-0	0.3 ppm TLV; 0.37 mg/m3 TLV; 0.6 ppm Binding STEL; 0.74 mg/m3 Binding STEL; Skin notation
Triethanolamine CAS # 102-71-6	5 mg/m3 TLV; 0.8 ppm TLV; 10 mg/m3 Indicative STEL; 1.6 ppm Indicative STEL; Skin notation

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.0 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.9	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formaldehyde 0.027 ppm odor threshold value (recognizable) Triethanolamine >10 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

Avoid exposure to heat and direct sunlight.

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Phosphoric Acid CAS # 7664-38-2	Dermal LD50 Rabbit 2740 mg/kg; Inhalation LC50 Rat >850 mg/m3 1 h; Oral LD50 Rat 1530 mg/kg
Formaldehyde CAS # 50-00-0	Dermal LD50 Rabbit 270 mg/kg; Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 100 mg/kg
Triethanolamine CAS # 102-71-6	Dermal LD50 Rabbit >20000 mg/kg; Oral LD50 Rat 4190 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation May cause mild skin irritation.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause an allergic skin reaction.

Carcinogenicity May cause cancer.

Formaldehyde is listed with OSHA as a carcinogen; NTP as known Human Carcinogen; IARC as Group 1 carcinogenic to humans; ACGIH as Group A2 Suspected Human Carcinogen; and 1272/2008 EC as Category 1B carcinogen.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Formaldehyde CAS # 50-00-0	96 h LC50 Pimephales promelas: 22.6 - 25.7 mg/L -through]; 96 h LC50 Lepomis macrochirus: 1510 µg/L [static]; 96 h LC50 Brachydanio rerio: 41 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 0.032 - 0.226 mL/L -through]; 96 h LC50 Oncorhynchus mykiss: 100 - 136 mg/L [static]; 96 h LC50 Pimephales promelas: 23.2 - 29.7 mg/L [static]
Triethanolamine CAS # 102-71-6	96 h LC50 Pimephales promelas: 10600 - 13000 mg/L -through]; 96 h LC50 Pimephales promelas: >1000 mg/L [static]; 96 h LC50 Lepomis macrochirus: 450 - 1000 mg/L [static]

Microtox No information available.

Water Flea

Formaldehyde CAS # 50-00-0	48 h LC50 Daphnia magna: 2 mg/L; 48 h EC50 Daphnia magna: 11.3 - 18 mg/L [Static]

Fresh Water Algae

Triethanolamine CAS # 102-71-6	72 h EC50 Desmodesmus subspicatus: 216 mg/L; 96 h EC50 Desmodesmus subspicatus: 169 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 50-00-0	Formaldehyde	0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7664-38-2	Phosphoric Acid
CAS # 50-00-0	Formaldehyde

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 50-00-0 Formaldehyde

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts Right To Know (RTK) List

CAS # 7664-38-2	Phosphoric Acid
CAS # 7757-82-6	Sodium Sulfate
CAS # 50-00-0	Formaldehyde
CAS # 102-71-6	Triethanolamine

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7664-38-2	Phosphoric Acid
CAS # 111-27-3	1-Hexanol
CAS # 50-00-0	Formaldehyde
CAS # 102-71-6	Triethanolamine

Pennsylvania Right To Know (RTK) List

CAS # 7664-38-2	Phosphoric Acid
CAS # 111-27-3	1-Hexanol
CAS # 7757-82-6	Sodium Sulfate
CAS # 50-00-0	Formaldehyde
CAS # 102-71-6	Triethanolamine

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Updated Section 1, 4, 8, 9, 11 - 16.	
Document version and issue/revision date		

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Section 16 Other Information (Continued)

Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20
Document ID: AUH1012-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H330 - Fatal if inhaled.
H331 - Toxic if inhaled.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program

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ISE Mid Standard Solution

Section 16 Other Information (Continued)

OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Issue Date 22-Jan-2015 **Revision Date** 22-Jan-2015 **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Product Name Klübersynth UH1 6-460

Other means of identification
Product code: 096060
Synonyms None

Recommended use of the chemical and restrictions on use
Recommended Use Lubricant.
Uses advised against Consumer use

Details of the supplier of the safety data sheet
Supplier Address
Klüber Lubrication NA, LP
32 Industrial Drive
Londonderry, NH 03053
Phone: (603) 647-4104
Fax: (603) 647-4106

Emergency telephone number
Emergency Telephone CHEMTREC: 1-800-424-9300; INTERNATIONAL: (703) 527-3887

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin sensitization	Category 1

Label elements

EMERGENCY OVERVIEW

Signal word
Warning

Hazard statements
May cause an allergic skin reaction

Appearance Oil **Physical state** Liquid **Odor** Mild

Precautionary Statements - Prevention
Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves
Skin IF ON SKIN: Wash with plenty of soap and water
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)
Other information
• Harmful to aquatic life with long lasting effects

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Components	CAS-No	Weight %	Trade Secret
N-Methyl-N-oleoylglycine	110-25-8	0.1-0.3	*

4. FIRST AID MEASURES

First aid measures

Eye contact: Flush eye with water for 15 minutes. If symptoms persist, call a physician.

Skin contact: Rinse with plenty of water. If skin irritation persists, call a physician.

Inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion. If symptoms persist, call a physician.

Ingestion: Do not induce vomiting. Consult a physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
Carbon dioxide (CO2). Dry chemical. Dry sand. Water spray mist or foam.

Unsuitable extinguishing media Do not use a solid water stream as it may scatter and spread fire
Specific hazards arising from the chemical
Thermal decomposition can lead to release of irritating gases and vapors. Water may be used to cool closed containers.

Explosion data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Special protective equipment for firefighters:
In the event of fire and/or explosion do not breathe fumes. In the event of fire, wear self-contained breathing apparatus. Standard procedure for chemical fires.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions: Contaminated surfaces will be extremely slippery. Avoid contact with skin, eyes and clothing. Wear personal protective equipment.

Environmental precautions

Environmental precautions: Do not allow material to contaminate ground water system. Prevent product from entering drains.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Soak up with oil absorbent material. Pick up and transfer to properly labelled containers. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Do not breathe vapors or spray mist. Avoid contact with skin, eyes and clothing. Spilling onto the container`s outside will make container slippery. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep cool. Keep in properly labelled containers. Keep away from heat and sources of ignition

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines Contains mineral oil, vegetable oil, and/or synthetic oil. Under conditions which may generate mists, observe the OSHA PEL of 5 mg/m^3, ACGIH STEL of 10 mg/m^3.

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Respiratory protection: No personal respiratory protective equipment normally required.
Hand protection: Impervious gloves
Eye protection: Safety glasses with side-shields Avoid contact with eyes.
Skin and body protection: Usual safety precautions while handling the product will provide adequate protection against this potential effect
General Hygiene Considerations Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Liquid
Appearance Oil **Odor** Mild **Color** Yellow **Odor threshold** No information available

Property	Values	Remarks • Method		
pH			Not applicable	

Melting point/freezing point	No information available	**Boiling point / boiling range**	No information available
Flash point	>= 220 °C / >= 428 °F ISO 2592	**Evaporation rate**	No information available
Flammability (solid, gas)	No information available	**Flammability Limit in Air**	
Upper flammability limit:	No information available	**Lower flammability limit:**	No information available
Vapor pressure	< 0.001 hPa, 20 °C	**Vapor density**	No information available
Specific Gravity	1.07	**Water solubility**	partially soluble
Solubility in other solvents	No information available	**Partition coefficient**	No information available
Autoignition temperature	No information available	**Decomposition temperature**	No information available
Kinematic viscosity	460 mm2/s @ 40 °C	**Dynamic viscosity**	No information available

Explosive properties No information available
Oxidizing properties No information available

Other information

Softening point No information available
Molecular weight No information available
VOC Content (%) No information available
Density No information available
Bulk density No information available

10. STABILITY AND REACTIVITY

Reactivity
Not applicable

Chemical stability

Stability Stable under normal conditions

Possibility of Hazardous Reactions

Possibility of Hazardous Reactions None under normal processing.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid

Conditions to avoid Heat, flames and sparks

Hazardous Decomposition Products

Hazardous Decomposition Products None under normal processing

Incompatible materials

Incompatible materials Strong oxidising agents

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information Product does not present an acute toxicity hazard based on known or supplied information

Eye contact Contact with eyes may cause irritation.

Skin contact	Prolonged contact may cause redness and irritation. May cause sensitization by skin contact.
Inhalation	Vapors and/or aerosols which may be formed at elevated temperatures may be irritating to eyes and respiratory tract.
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

Information on toxicological effects

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization	May cause sensitization by skin contact.
Mutagenic effects:	Did not show mutagenic or teratogenic effects in animal experiments.
Carcinogenicity	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.
Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
STOT - Single Exposure	None under normal use conditions.
STOT - Repeated Exposure	None under normal use conditions.
Aspiration hazard	Not applicable.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	5164 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Harmful to aquatic life with long lasting effects

0% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability
No information available.

Bioaccumulation
No information available.

Mobility
No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. TRANSPORT INFORMATION

DOT	Not Regulated by any means of transportation

15. REGULATORY INFORMATION

International Inventories

TSCA:	Listed in TSCA
DSL:	All of the components in this product are listed in DSL
EINECS/ELINCS	This product complies with EINECS/ELINCS
CHINA:	This product complies with China IECSC.
KECL:	This product does not comply with Korea KECL.
PICCS:	This product does not comply with Philippines PICCS.
AICS:	All the constituents of this material are listed on the Australian AICS

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

State Regulations (RTK)

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

Nfpa:
Health: 1
Flammability: 1
Instability 0
NFPA/HMIS * for Carc, Muta, Tera, Specific Organ *
HMIS health rating:
Health: 2
Flammability: 1
Physical hazards 0
Personal protection B

Issue Date	22-Jan-2015
Revision Date	22-Jan-2015

Revision Note
Not applicable

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End of Safety Data Sheet

Kolorsafe dry BASE neutralizer

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Revision Date: 03/07/2014 Date of issue: 03/07/2014 Version: 1.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product Form: Mixture

Product Name: Kolorsafe dry BASE neutralizer

Product Code: 4500 Series

Intended Use of the Product

Spill cleanup/ Neutralize caustic. For professional use only.

Name, Address, and Telephone of the Responsible Party

Company

NPS Corp
3303 Spirit Way
Green Bay, WI 54304
(920) 983-9223
web: www.npscorp.com
email: cs@npscorp.com

Emergency Telephone Number

Emergency number : (800) 424-9300 (USA); +1 (703) 527-3887 (International and Maritime) CHEMTREC

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

Classification (GHS-US)

Comb. Dust

Eye Irrit. 2A H319

Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

GHS07

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : May form combustible dust concentrations in air
H319 - Causes serious eye irritation

Precautionary Statements (GHS-US) : P264 - Wash hands, forearms, and exposed areas thoroughly after handling
P280 - Wear eye protection, protective clothing, protective gloves
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 - If eye irritation persists: Get medical advice/attention

Other Hazards Not available

Unknown Acute Toxicity (GHS-US) Not available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Citric acid	(CAS No) 77-92-9	99.983	Comb. Dust Eye Irrit. 2A, H319

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

Inhalation: If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical advice.
Skin Contact: Remove contaminated clothing. Rinse affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.
Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
Ingestion: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER/doctor/physician if you feel unwell.

Most Important Symptoms and Effects Both Acute and Delayed

General: Causes serious eye irritation.
Inhalation: Dust from this product may cause irritation to the respiratory tract.
Skin Contact: May cause mild skin irritation.
Eye Contact: Causes serious eye irritation.
Ingestion: Ingestion is likely to be harmful or have adverse effects.
Chronic Symptoms: Repeated or prolonged skin contact may cause dermatitis and defatting.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.
Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible Dust.
Explosion Hazard: Avoid dust clouds in combination with static electricity.
Reactivity: Dust clouds can be explosive.

Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products: Carbon oxides (CO, CO_2).

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Consider the risk of potentially explosive atmospheres. Avoid generating dust. Keep away from open flames, hot surfaces and sources of ignition. No smoking. Avoid all contact with skin, eyes, or clothing. Avoid breathing dust.

For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).
Emergency Procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.
Emergency Procedures: Ventilate area. Eliminate ignition sources. Stop leak if safe to do so.

Environmental Precautions

Avoid release to the environment.

Methods and Material for Containment and Cleaning Up

For Containment: Avoid generation of dust during clean-up of spills.
Methods for Cleaning Up: Use only non-sparking tools. Clear up spills immediately and dispose of waste safely.

Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

Kolorsafe dry BASE neutralizer

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible Materials: Strong bases. Strong oxidizers. Metals.

Storage Temperature: < 65.5 °C (150 °F)

Specific End Use(s)

Spill cleanup/ Neutralize caustic. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

Exposure Controls

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Avoid high dust concentration. Use explosion-proof equipment. Ensure all national/local regulations are observed. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Safety glasses. Gloves. Protective clothing. Insufficient ventilation: wear respiratory protection.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use NIOSH-approved air-purifying or supplied-air respirator where airborne concentrations of dust are expected to exceed exposure limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	:	Solid
Appearance	:	Bluish-White Crystalline Powder
Odor	:	Odorless
Odor Threshold	:	Not available
pH	:	Not available
Relative Evaporation Rate (butylacetate=1)	:	Not available
Melting Point	:	Not available
Freezing Point	:	Not available
Boiling Point	:	Not available
Flash Point	:	Not available
Auto-ignition Temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not available
Lower Flammable Limit	:	Not available
Upper Flammable Limit	:	Not available
Vapor Pressure	:	Not available
Relative Vapor Density at 20 °C	:	Not available
Relative Density	:	Not available
Specific Gravity	:	Not available

Solubility	:	Not available
Log Pow	:	Not available
Log Kow	:	Not available
Viscosity, Kinematic	:	Not available
Viscosity, Dynamic	:	Not available
Explosive properties	:	Dust explosion hazard in air
Explosion Data – Sensitivity to Mechanical Impact	:	Not available
Explosion Data – Sensitivity to Static Discharge	:	Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Dust clouds can be explosive.
Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
Conditions to Avoid: Avoid creating or spreading dust. Direct sunlight. Extremely high or low temperatures.
Incompatible Materials: Strong bases. Strong oxidizers. Metals.
Hazardous Decomposition Products: Carbon oxides (CO, CO_2).

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute Toxicity : Not classified
LD50 and LC50 Data Not available
Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Causes serious eye irritation.
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Aspiration Hazard: Not classified
Symptoms/Injuries After Inhalation: Dust from this product may cause irritation to the respiratory tract.
Symptoms/Injuries After Skin Contact: May cause mild skin irritation.
Symptoms/Injuries After Eye Contact: Causes serious eye irritation.
Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.
Chronic Symptoms: Repeated or prolonged skin contact may cause dermatitis and defatting.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Citric acid (77-92-9)	
LD50 Oral Rat	5400 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
ATE (oral)	5400.000 mg/kg body weight

SECTION 12: ECOLOGICAL INFORMATION

Toxicity Not classified

Citric acid (77-92-9)	
LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

Persistence and Degradability

Kolorsafe dry BASE neutralizer	
Persistence and Degradability	Not established.

Citric acid (77-92-9)	
Persistence and Degradability	Readily biodegradable in water.

Kolorsafe dry BASE neutralizer

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Bioaccumulative Potential

Kolorsafe dry BASE neutralizer	
Bioaccumulative Potential	Not established.

Citric acid (77-92-9)	
Log Pow	-1.72 (at 20 °C)

Mobility in Soil Not available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

Additional Information Not available

Transport by sea Not regulated for transport

Air transport Not regulated for transport

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

Kolorsafe dry BASE neutralizer	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Fire hazard

Citric acid (77-92-9)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations

Citric acid (77-92-9)
U.S. - Texas - Effects Screening Levels - Long Term
U.S. - Texas - Effects Screening Levels - Short Term

Canadian Regulations

Kolorsafe dry BASE neutralizer	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

Citric acid (77-92-9)	
Listed on the Canadian DSL (Domestic Substances List) inventory. Listed on the Canadian Ingredient Disclosure List	
WHMIS Classification	Class E - Corrosive Material

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION

Revision date : 03/07/2014

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Comb. Dust	Combustible Dust

Kolorsafe dry BASE neutralizer

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Comb. Dust	May form combustible dust concentrations in air
H319	Causes serious eye irritation

Party Responsible for the Preparation of This Document

NPS Corp

Phone Number: +1 (920) 983-9223

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

North America GHS US 2012 & WHMIS

Kit SDS Cover Sheet

Doc. ID: OSR6127-75: Rev. 04
Revised (year/month/day) 2015/03/20

Product Information

Product Name	**LDH**
Part Number	OSR6127, OSR6227

Components

Description	LDH R1 LDH R2

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: OSR6127-75 Rev. 04
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name LDH R1

Part Number Component of P/N OSR6127, OSR6227

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

For full text of R- phrases: see Section 16.

Colorless; Clear; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

2-Amino-2-methyl-1-propanol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

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Section 3 Composition and Information on Ingredients (Continued)

2-Amino-2-methyl-1-propanol CAS # 124-68-5 EINECS # 204-709-8 Index # 603-070-00-6	2 - 5	Xi;R36/38 R52/53	Aquatic Longterm 3 Eye Irrit. 2 Skin Irrit. 2 H315; H319; H412	Acute Tox. Dermal 5 Acute Tox. Oral 5 Aquatic Longterm 3 Eye Irrit. 2 Skin Irrit. 2 H303; H313; H315; H319; H412	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

Exposure may result in irritation of skin and eyes.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

	Flammable Properties	Nonflammable aqueous solution.
5.1	**Extinguishing Media**	In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.
5.2	**Special hazards arising from the substance or mixture**	
	Special Fire and Explosion Hazards	
		No special hazards determined.
	Hazardous Combustion Products	
		No combustion products posing significant hazards are expected from this product (an aqueous solution).
5.3	**Advice for fire fighters**	
	Protective Equipment	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1	**Personal precautions, protective equipment and emergency procedures**	
	Personal Precautions	Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.
6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	Use good laboratory procedures; avoid eye and skin contact.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

2-Amino-2-methyl-1-propanol
CAS # 124-68-5

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.010 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	9.4 @20°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0 °C	**Auto-ignition Temp.**	Product is not selfigniting
Boiling Point	Similar to water, approximately 100 °C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid

Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

2-Amino-2-methyl-1-propanol CAS # 124-68-5	Oral LD50 Rat 2900 mg/kg; Dermal LD50 Rabbit >2000 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation May cause skin irritation.

Serious eye damage/eye irritation May cause eye irritation.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

2-Amino-2-methyl-1-propanol CAS # 124-68-5	96 h LC50 Lepomis macrochirus: 190 mg/L [static]
Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Microtox No information available.

Water Flea

2-Amino-2-methyl-1-propanol CAS # 124-68-5	48 h EC50 Daphnia magna: 193 mg/L

Fresh Water Algae

2-Amino-2-methyl-1-propanol CAS # 124-68-5	72 h EC50 Desmodesmus subspicatus: 520 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL 2-Amino-2-methyl-1-propanol is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

2-Amino-2-methyl-1-propanol is listed.
Sodium Azide is listed.

Pennsylvania RTK 2-Amino-2-methyl-1-propanol is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S37 Wear suitable gloves.
S60 This material and/or its container must be disposed of as hazardous waste.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

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Global SDS – English

Section 15 Regulatory Information (Continued)

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

T - Toxic

T+ - Very toxic

Xi - Irritant

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R36/38 Irritating to eyes and skin.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5

Eye Irrit. 2 - Eye Irritation Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Aquatic Longterm 3 - Aquatic Hazard Long term, Category 3

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Irrit. 2 - Skin Irritation Category 2

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H303 - May be harmful if swallowed

H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

H313 - May be harmful In contact with skin
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H412 - Harmful to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: OSR6127-75 Rev. 04
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name LDH R2

Part Number Component of P/N OSR6127, OSR6227

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

For full text of R- phrases: see Section 16.

Colorless; Clear; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

DFG MAK None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.020 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	5.6 @20°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0 °C	**Auto-ignition Temp.**	Product is not selfigniting
Boiling Point	Similar to water, approximately 100 °C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

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Global SDS – English

Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S37 Wear suitable gloves.
S60 This material and/or its container must be disposed of as hazardous waste.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T - Toxic

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - Internal Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

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Section 16 Other Information (Continued)

NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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BECKMAN COULTER
LDL-Cholesterol Calibrator

SAFETY DATA SHEET

Document ID: ODC0024-75 Version 04
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name LDL-Cholesterol Calibrator

Part Number ODC0024

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light yellow; Opaque; Lyophilized Powder; Odorless

according to EC 1272/2008 (CLP/GHS)

Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Azide

Pictogram

None

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LDL-Cholesterol Calibrator

Section 2 Hazards (Continued)

Signal Word

None

Hazard Statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

This product contains Sodium azide which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	0.1 - 0.5	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

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Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for
Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.

If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder	**Gravity (Water=1.0)**	Not determined
Color	Light yellow	**Solubility**	
Transparency	Opaque	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	Not determined	**Partition n-octanol/water**	Not determined
Melting Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

This product contains Sodium azide which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
Avoid contact with incompatible materials.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	Harmful to aquatic life with long lasting effects. This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 4, 6, 8, 11 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20
Document ID: ODC0024-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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LDL-Cholesterol Calibrator

SAFETY DATA SHEET

Document ID: ODC0024-75 Version 04
Revision Date (year/month/day) 2019/04/11
Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: IM3302-75: Rev. AB
Revised (year/month/day) 2015/05/04

Product Information

Product Name LH IRMA

Part Number IM3302

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

125I-Labeled Anti-LH Monoclonal Antibody
LH IRMA Calibrators
LH IRMA Control
Wash Solution (20X)

Transport Information

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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Global SDS – English

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SAFETY DATA SHEET

Doc. ID: IM3302-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name 125I-Labeled Anti-LH Monoclonal Antibody

Part Number Component of P/N IM3302

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Red; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

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Section 4 First Aid Measures (Continued)

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of all waste material in accordance with local and facility guidelines.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Radioactive material is subject to the regulations of each country.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Red	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	2910	2910	2910	2910	PIN - 2910
14.2	Shipping Name	Radioactive Material, excepted package-limited quantity of material				
14.3	Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
14.4	Packing Group					
	Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Additional information					
	IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	161	Not applicable	161
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Iodine 125 has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 2910

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM3302-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name LH IRMA Calibrators

Part Number Component of P/N IM3302

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use Data given is for reconstituted solution.
For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Lyophilized Powder - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	Not applicable	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM3302-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name LH IRMA Control

Part Number Component of P/N IM3302

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Lyophilized - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	Not applicable	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65 Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.

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Section 16 Other Information (Continued)

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LC50 - Lethal Concentration, 50%

LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Doc. ID: IM3302-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Wash Solution (20X)

Part Number Component of P/N IM3302

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Toxic to Reproductive Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Boric Acid
Sodium Borate Decahydrate

Pictogram

Signal Word

DANGER

Hazard Statements

H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations
Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Borate Decahydrate CAS # 1303-96-4 EINECS # 237-560-2 Index # 005-011-01-1	0.1-0.3	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
Boric Acid CAS # 10043-35-3 EINECS # 233-139-2 Index # Not available	0.1-0.3	T;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC

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Section 3 Composition and Information on Ingredients (Continued)

SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.
Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Borate Decahydrate CAS # 1303-96-4	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)
Boric Acid CAS # 10043-35-3	6 mg/m3 STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m3 TWA (inhalable fraction) (listed under Borate compounds, inorganic)

DFG MAK

Boric Acid CAS # 10043-35-3	10 mg/m3 Peak (as B) (inhalable fraction); 10 mg/m3 TWA MAK (inhalable fraction) (as B)

Ireland

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA

IOELVs

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

NIOSH

Sodium Borate Decahydrate CAS # 1303-96-4	5 mg/m3 TWA

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.3	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Borate Decahydrate CAS # 1303-96-4	Oral LD50 Rat 2660 mg/kg
Boric Acid CAS # 10043-35-3	Oral LD50 Rat 2660 mg/kg; Inhalation LC50 Rat >0.16 mg/L 4 h; Dermal LD50 Rabbit >2000 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	May damage fertility or the unborn child.
Specific target organ toxicity – single exposure	No data available.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

Microtox No information available.

Water Flea

Boric Acid
CAS # 10043-35-3 — 48 h EC50 Daphnia magna: 115 - 153 mg/L

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Borate Decahydrate is listed.

New Jersey Dept. of Health RTK List

Sodium Borate Decahydrate is listed.

Pennsylvania RTK Sodium Borate Decahydrate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Borate Decahydrate
Boric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

T - Toxic
Repr. Cat. 2 - Toxic for Reproduction Category 2

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Section 16 Other Information (Continued)

	R60 May impair fertility. R61 May cause harm to unborn child. Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5 Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5 Skin Irrit. 3 - Skin Irritation Category 3 Repr. 1B - Toxic to Reproductive Category 1B H303 - May be harmful if swallowed H313 - May be harmful In contact with skin H316 - Causes mild skin irritation. H360 - May damage fertility or the unborn child.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name LIH

Part Number OSR62166

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Lismeehan O'Callaghan's Mills Co. Clare Ireland Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Aquatic Hazard Long term, Category 3

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.5.4% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

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Section 3 Composition and Information on Ingredients (Continued)

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

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Section 6 Accidental Release Measures (Continued)

	Personal Precautions	Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.
6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	Use good laboratory procedures; avoid eye and skin contact.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 2 to 25°C , as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	None established
	DFG MAK	None established
	Ireland	None established
	IOELVs	None established
	NIOSH	None established
	Japan	None established
	Sweden (AFS 2015:7 and amendments)	
		None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	6.8 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Update of product hazard and label elements in Sec. 2.
Updated hazard of pure ingredient in Sec. 3.
Updated Section 4, 12, 16.

Document version and issue/revision date

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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A
H301 - Toxic if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods

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Section 16 Other Information (Continued)

IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/19/2020 Reviewed on 06/19/2020

1 Identification

· **Product identifier**

· **Trade name: Liquichek™ Cardiac Markers Control LT**

· **Catalog or product number:** 649, 649X
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**		
Proprietary Reagent BS 11	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	0.1-1%

· **Additional information**
Contains added constituents of animal origin.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/19/2020 Reviewed on 06/19/2020

Trade name: Liquichek™ Cardiac Markers Control LT

(Contd. of page 1)

Contains human sourced and/or potentially infectious components.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed**
Skin irritation
Eye irritation
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Clean the affected area carefully; suitable cleaners are:
Disinfectant
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/19/2020 Reviewed on 06/19/2020

Trade name: Liquichek™ Cardiac Markers Control LT

(Contd. of page 2)

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
107-21-1 ethane-1,2-diol	
TLV (United States)	Short-term value: 10** mg/m³, 50* ppm Long-term value: 25* ppm *vapor fraction:**inh. fraction, aerosol only
WEEL (United States)	I (2)

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Liquid
Color:	Light yellow
· **Odor:**	Light

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/19/2020 Reviewed on 06/19/2020

Trade name: Liquichek™ Cardiac Markers Control LT

(Contd. of page 3)

· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	6.2
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not determined.
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Solids content:	15.9 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.

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Trade name: Liquichek™ Cardiac Markers Control LT

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· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· LD/LC50 values for hazardous components per OSHA criteria:		
Proprietary Component C		
Oral	LD50	15,900 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
56-75-7	chloramphenicol	2A

· NTP (National Toxicology Program)		
56-75-7	chloramphenicol	R

· OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/19/2020 Reviewed on 06/19/2020

Trade name: Liquichek™ Cardiac Markers Control LT

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13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7778-80-5	potassium sulfate	ACTIVE
	Proprietary Component C	ACTIVE
	Proprietary Component D, sugar	ACTIVE
	Proprietary Reagent J	ACTIVE

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Trade name: Liquichek™ Cardiac Markers Control LT

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7447-40-7	potassium chloride	ACTIVE
	Proprietary Reagent MS 1	ACTIVE
107-21-1	ethane-1,2-diol	ACTIVE
	Proprietary Reagent BS 11	ACTIVE
	Proprietary Reagent KC	ACTIVE
	Proprietary Reagent MS2	ACTIVE
	Proprietary Reagent J19	ACTIVE
	Proprietary Reagent J17	ACTIVE
56-75-7	chloramphenicol	ACTIVE
1405-10-3	Neomycin, sulfate (salt)	ACTIVE
	Proprietary Reagent KX	ACTIVE
71-63-6	digitoxin	ACTIVE

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Developmental Toxicity**

107-21-1	ethane-1,2-diol
1405-10-3	Neomycin, sulfate (salt)

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.

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Trade name: Liquichek™ Cardiac Markers Control LT

(Contd. of page 7)

· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· ***** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/28/2019 Reviewed on 06/28/2019

1 Identification

· **Product identifier**

· **Trade name: Liquichek Cardiac Markers Plus Control LT**

· **Catalog or product number:**
146, 147, 148, 149, 146X, 147X, 148X, 149X, 297, 298, 299, 298X, 27104, 27105, 27106, 27104X, 27105X, 27106X, 12004806, 12004807, 12004808, 12004809, 12004810, 12004811, 12004812, 12004813, 12004814, 12004815, 12004816, 12004817
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

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Safety Data Sheet
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Trade name: Liquichek Cardiac Markers Plus Control LT

(Contd. of page 1)

· **Listing of dangerous and non-hazardous components:**

	Proprietary Reagent BS 11 Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	0.1-1%
CAS: 56-75-7 EINECS: 200-287-4	chloramphenicol Carc. 1B, H350	0.001-0.01%

· **Additional information**
Contains added constituents of animal origin.
Contains human sourced and/or potentially infectious components.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Allow to solidify. Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
· **Reference to other sections** See Section 13 for disposal information.

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acc. to OSHA HCS

Printing date 06/28/2019 Reviewed on 06/28/2019

Trade name: Liquichek Cardiac Markers Plus Control LT

(Contd. of page 2)

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
56-75-7 chloramphenicol	
WEEL (United States)	Long-term value: 0.5 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
Form: Liquid
Color: Light yellow

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/28/2019 Reviewed on 06/28/2019

Trade name: Liquichek Cardiac Markers Plus Control LT

(Contd. of page 3)

· **Odor:**	Mild
· **pH-value at 20 °C:**	5.95-6.45
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with Water:**	Fully miscible
· **Solvent content:**	
Solids content:	9.8 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values for hazardous components per OSHA criteria:**		
Proprietary Component C		
Oral	LD50	15,900 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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acc. to OSHA HCS

Printing date 06/28/2019 Reviewed on 06/28/2019

Trade name: Liquichek Cardiac Markers Plus Control LT

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· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
56-75-7	chloramphenicol	2A

· **NTP (National Toxicology Program)**		
56-75-7	chloramphenicol	R

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek Cardiac Markers Plus Control LT

(Contd. of page 5)

· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

None of the ingredients is listed.

· **Section 313 (40CFR372.65):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

	Proprietary Reagent BS 10	ACTIVE
	Proprietary Component C	ACTIVE
	Proprietary Reagent BS 11	ACTIVE
	Proprietary Reagent MS2	ACTIVE
	Proprietary Reagent J19	ACTIVE
	Proprietary Reagent J17	ACTIVE
	Proprietary Reagent KC	ACTIVE
1405-10-3	Neomycin, sulfate (salt)	ACTIVE
56-75-7	chloramphenicol	ACTIVE
	Proprietary Reagent KX	ACTIVE
71-63-6	digitoxin	ACTIVE
9001-15-4	Kinase (phosphorylating), creatine	ACTIVE

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Developmental Toxicity**

1405-10-3	Neomycin, sulfate (salt)

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Printing date 06/28/2019 Reviewed on 06/28/2019

Trade name: Liquichek Cardiac Markers Plus Control LT

(Contd. of page 6)

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Carc. 1B: Carcinogenicity – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2016 Reviewed on 09/19/2016

1 Identification

· **Product identifier**

· **Trade name: Liquichek™ Immunology Control**

· **Catalog or product number:**
591, 592, 593, 594, 595, 596, 590X, 281, 282, 283, 282X, 12003784, 12003785, 12003786, 12003787
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2016 Reviewed on 09/19/2016

Trade name: Liquichek™ Immunology Control

(Contd. of page 1)

· **Listing of dangerous and non-hazardous components:**

	Proprietary Component C	2.5-5%
	Proprietary Reagent BS 10	2.5-5%
CAS: 9007-83-4 EINECS: 285-365-6	gamma globulin	1.0-2.5%
EINECS: 268-338-3	Human Source Material	50-100%

· **Additional information** Contains human sourced and/or potentially infectious components.

4 First-aid measures

· **Description of first aid measures**
· **General information**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Keep contaminated washing water and dispose of appropriately.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunology Control

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· **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
26628-22-8 sodium azide	
REL (United States)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (United States)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

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BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunology Control

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Liquid
Color:	Light yellow
· **Odor:**	Light
· **pH-value at 20 °C:**	7.6-8.2
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with**	
Water:	Not determined.
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	9.5 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions**
This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values for hazardous components per OSHA criteria:**

Proprietary Component C		
Oral	LD50	15900 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritant effect.

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunology Control

(Contd. of page 4)

· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunology Control

(Contd. of page 5)

· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

*
15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
26628-22-8	sodium azide

· **Section 313 (40CFR372.65):**	
26628-22-8	sodium azide

· **TSCA (Toxic Substances Control Act):**	
	Proprietary Component C
	Proprietary Reagent BS 10
	Proprietary Reagent A
	Proprietary Reagent J13
	Proprietary Reagent J12
26628-22-8	sodium azide

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**		
	Proprietary Reagent BS 10	A4
26628-22-8	sodium azide	A4

· **MAK (German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunology Control

(Contd. of page 6)

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/19/2016 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· *** Data compared to the previous version altered.**

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/20/2016 Reviewed on 10/20/2016

1 Identification

· **Product identifier**

· **Trade name: Liquichek™ Immunoassay Plus Control, Level 3**

· **Catalog or product number:** 363, 269, 12004321
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/20/2016 Reviewed on 10/20/2016

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

(Contd. of page 1)

· **Listing of dangerous and non-hazardous components:**

CAS: 57-13-6 EINECS: 200-315-5	urea		0.01-0.1%
CAS: 56-75-7 EINECS: 200-287-4	chloramphenicol	Carc. 1B, H350	.001-.01%
EINECS: 268-338-3	Human Source Material		50-100%
	Proprietary Reagent KK		1.0-2.5%
	Proprietary Component C		1.0-2.5%
	Proprietary Reagent BS 10		1.0-2.5%

· **Additional information**
Contains human sourced and/or potentially infectious components.
Contains added constituents of animal origin.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/20/2016 *Reviewed on 10/20/2016*

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

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Disinfectant
· **Reference to other sections** *See Section 13 for disposal information.*

7 Handling and storage

· **Handling**
· **Precautions for safe handling** *No special precautions are necessary if used correctly.*
· **Information about protection against explosions and fires:** *No special measures required.*

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** *According to product specification*
· **Information about storage in one common storage facility:** *Not required.*
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** *No further relevant information available.*

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** *No further data; see item 7.*

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
57-13-6 urea	
WEEL (United States)	Long-term value: 10 mg/m³
56-75-7 chloramphenicol	
WEEL (United States)	Long-term value: 0.5 mg/m³
26628-22-8 sodium azide	
REL (United States)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (United States)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

· **Additional information:** *The lists that were valid during the creation were used as basis.*

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** *Not required.*
· **Protection of hands:** *Protective gloves.*
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 4)

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

(Contd. of page 3)

· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Light yellow
· **Odor:**	Light
· **pH-value at 20 °C:**	7.2-7.4
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	7.3 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions**
This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

(Contd. of page 4)

· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3
56-75-7	chloramphenicol	2A
58-08-2	caffeine	3

· **NTP (National Toxicology Program)**		
56-75-7	chloramphenicol	R
630-93-3	Phenytoin Sodium	R
57-83-0	progesterone	R

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 10/20/2016 Reviewed on 10/20/2016

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

(Contd. of page 5)

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **ADR, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
20830-75-5	digoxin

· **Section 313 (40CFR372.65):**	
554-13-2	lithium carbonate

· **TSCA (Toxic Substances Control Act):**	
	Proprietary Reagent KK
	Proprietary Component C
	Proprietary Reagent BS 10
7647-14-5	sodium chloride
	Proprietary Reagent KG
69-72-7	Salicylic acid
7447-40-7	potassium chloride
57-13-6	urea
7558-79-4	disodium hydrogenorthophosphate
103-90-2	paracetamol
554-13-2	lithium carbonate

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Safety Data Sheet
acc. to OSHA HCS

Printing date 10/20/2016 Reviewed on 10/20/2016

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

(Contd. of page 6)

15687-27-1	ibuprofen
69-93-2	uric acid
58-55-9	theophylline
56-75-7	chloramphenicol
58-08-2	caffeine
630-93-3	Phenytoin Sodium
113-52-0	imipramine hydrochloride
9034-40-6	Luteinizing hormone-releasing hormone
20830-75-5	digoxin
60-27-5	Creatinine
57-83-0	progesterone
56-54-2	quinidine
58-22-0	testosterone
52-39-1	aldosterone
549-18-8	amitriptyline hydrochloride
68-19-9	cyanocobalamin
50-23-7	hydrocortisone
7732-18-5	water

· **California Proposition 65:**

· **Chemicals known to cause cancer:**	
50-06-6	phenobarbital
630-93-3	Phenytoin Sodium
50-28-2	estradiol
57-83-0	progesterone
58-22-0	testosterone

· **Developmental Toxicity**	
554-13-2	lithium carbonate
298-46-4	Carbamazepin
32986-56-4	tobramycin
1405-41-0	Gentamicin Sulfate

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**		
57-13-6	urea	II

· **TLV (Threshold Limit Value established by ACGIH)**		
	Proprietary Reagent BS 10	A4
26628-22-8	sodium azide	A4

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Immunoassay Plus Control, Level 3

(Contd. of page 7)

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 10/20/2016 / -
· **Abbreviations and acronyms:**
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Carc. 1B: Carcinogenicity – Category 1B
· *** Data compared to the previous version altered.**

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2017 Reviewed on 08/04/2017

1 Identification

· **Product identifier**

· **Trade name: Liquichek™ Urine Chemistry Control**

· **Catalog or product number:** 397, 398, 395X, 195, 196, 198X, 12004329, 12004330, 12004331
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards**
Contains human sourced and/or potentially infectious components.
Contains components derived from human urine.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2017 Reviewed on 08/04/2017

Trade name: Liquichek™ Urine Chemistry Control

(Contd. of page 1)

· **Listing of dangerous and non-hazardous components:**

CAS: 57-13-6 EINECS: 200-315-5	urea	1.0-2.5%
CAS: 4432-31-9 EINECS: 224-632-3	2-morpholinoethanesulphonic acid Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	1.0-2.5%
CAS: 12125-02-9 EINECS: 235-186-4	ammonium chloride Acute Tox. 4, H302; Eye Irrit. 2A, H319	.001-.01%

· **Additional information**
Contains human sourced and/or potentially infectious components.
Contains components derived from human urine.
Contains added constituents of animal origin.

4 First-aid measures

· **Description of first aid measures**
· **General information**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed**
Skin irritation
Eye irritation
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

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Disinfectant
· **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
57-13-6 urea	
WEEL (United States)	Long-term value: 10 mg/m³
26628-22-8 sodium azide	
REL (United States)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (United States)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3
12125-02-9 ammonium chloride	
REL (United States)	Short-term value: 20 mg/m³ Long-term value: 10 mg/m³
TLV (United States)	Short-term value: 20 mg/m³ Long-term value: 10 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2017 Reviewed on 08/04/2017

Trade name: Liquichek™ Urine Chemistry Control

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Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Light yellow
· **Odor:**	Light
· **pH-value at 20°C:**	6.0-6.5
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	5.5 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions**
This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquichek™ Urine Chemistry Control

(Contd. of page 4)

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** Irritant to skin and mucous membranes.
· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2017 Reviewed on 08/04/2017

Trade name: Liquichek™ Urine Chemistry Control

(Contd. of page 5)

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
26628-22-8	sodium azide

· **Section 313 (40CFR372.65):**	
26628-22-8	sodium azide

· **TSCA (Toxic Substances Control Act):**	
57-13-6	urea
4432-31-9	2-morpholinoethanesulphonic acid
7647-14-5	sodium chloride
7447-40-7	potassium chloride
50-99-7	glucose
7778-77-0	potassium dihydrogenphosphate
60-27-5	Creatinine
9048-46-8	Bovine Serum Albumin
26628-22-8	sodium azide
	Proprietary Reagent KM

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Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2017 Reviewed on 08/04/2017

Trade name: Liquichek™ Urine Chemistry Control

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69-93-2	uric acid
70024-90-7	Human Serum Albumin (HSA)
9000-90-2	Amylase, alpha-
50-23-7	hydrocortisone
26172-55-4	5-chloro-2-methyl-2H-isothiazol-3-one
2682-20-4	2-methyl-2H-isothiazol-3-one
12125-02-9	ammonium chloride

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**		
57-13-6	urea	II

· **TLV (Threshold Limit Value established by ACGIH)**		
26628-22-8	sodium azide	A4

· **MAK (German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 08/04/2017 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

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Safety Data Sheet
acc. to OSHA HCS

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Trade name: Liquichek™ Urine Chemistry Control

(Contd. of page 7)

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Printing date 01/27/2017 Reviewed on 01/27/2017

1 Identification

· **Product identifier**

· **Trade name: Liquid Assayed Multiqual®**

· **Catalog or product number:** 694, 695, 696, 695X, 337, 338, 339, 338X
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**			
EINECS: 268-338-3	Human Source Material		50-100%

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Safety Data Sheet
acc. to OSHA HCS

Printing date 01/27/2017 Reviewed on 01/27/2017

Trade name: Liquid Assayed Multiqual®

(Contd. of page 1)

	Proprietary Reagent KK		2.5-5%
CAS: 57-13-6 EINECS: 200-315-5	urea		0.1-1.0%
CAS: 7646-85-7 EINECS: 231-592-0	zinc chloride	Skin Corr. 1B, H314 Acute Tox. 4, H302	.001-.01%

· **Additional information**
Contains human sourced and/or potentially infectious components.
Contains added constituents of animal origin.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** Eye irritation
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
· **Reference to other sections** See Section 13 for disposal information.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 01/27/2017 Reviewed on 01/27/2017

Trade name: Liquid Assayed Multiqual®

(Contd. of page 2)

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
64-17-5 ethanol	
PEL (United States)	Long-term value: 1900 mg/m³, 1000 ppm
REL (United States)	Long-term value: 1900 mg/m³, 1000 ppm
TLV (United States)	Short-term value: 1880 mg/m³, 1000 ppm
57-13-6 urea	
WEEL (United States)	Long-term value: 10 mg/m³
7646-85-7 zinc chloride	
PEL (United States)	Long-term value: 1 mg/m³ Fume
REL (United States)	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³
TLV (United States)	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³ fume

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves

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Safety Data Sheet
acc. to OSHA HCS

Printing date 01/27/2017 Reviewed on 01/27/2017

Trade name: Liquid Assayed Multiqual®

(Contd. of page 3)

· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Amber
· **Odor:**	Odorless
· **pH-value at 20 °C:**	7.7 - 7.9
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Density:**	Not determined
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Solvent content:**	
Organic solvents:	0.2 %
Solids content:	6.2 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

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*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
57-88-5	cholesterol	3
64-17-5	ethanol	1
103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3

· **NTP (National Toxicology Program)**		
630-93-3	Phenytoin Sodium	R

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 01/27/2017 Reviewed on 01/27/2017

Trade name: Liquid Assayed Multiqual®

(Contd. of page 5)

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13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

*
15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
20830-75-5	digoxin

· **Section 313 (40CFR372.65):**	
7646-85-7	zinc chloride

· **TSCA (Toxic Substances Control Act):**	
	Proprietary Reagent KK
7647-14-5	sodium chloride
	Proprietary Reagent MS 1
50-99-7	glucose
657-27-2	lysine hydrochloride
57-88-5	cholesterol

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Safety Data Sheet
acc. to OSHA HCS

Printing date 01/27/2017 Reviewed on 01/27/2017

Trade name: Liquid Assayed Multiqual®

(Contd. of page 6)

144-55-8	sodium hydrogencarbonate
64-17-5	ethanol
57-13-6	urea
7757-82-6	sodium sulphate
7447-40-7	potassium chloride
7778-77-0	potassium dihydrogenphosphate
69-72-7	Salicylic acid
103-90-2	paracetamol
7447-41-8	lithium chloride

· **California Proposition 65:**

· **Chemicals known to cause cancer:**	
50-06-6	phenobarbital
630-93-3	Phenytoin Sodium

· **Developmental Toxicity**	
64-17-5	ethanol
99-66-1	2-propylvaleric acid
298-46-4	Carbamazepin
1405-41-0	Gentamicin Sulfate
32986-56-4	tobramycin

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**		
57-13-6	urea	II
7646-85-7	zinc chloride	D, I, II

· **TLV (Threshold Limit Value established by ACGIH)**		
64-17-5	ethanol	A3

· **MAK (German Maximum Workplace Concentration)**		
64-17-5	ethanol	5

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Technical instructions (air):**

Class	Share in %
NK	0.1-1.0

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Liquid Assayed Multiqual®

(Contd. of page 7)

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 01/27/2017 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/13/2015

1 Identification

· **Product identifier**

· **Trade name: Lyphochek® Immunoassay Plus Control**

· **Catalog or product number:** 370, 371, 372, 373, 370X
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**		
EINECS: 268-338-3	Human Source Material	50-100%

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	Proprietary Reagent KK	0-20%
	Proprietary Reagent RF I	0-20%
	Proprietary Reagent KF	0-20%
CAS: 6131-90-4	Sodium Acetate 3-Hydrate	2.5-5%
CAS: 57-13-6 EINECS: 200-315-5	urea	0.1-1.0%
CAS: 56-75-7 EINECS: 200-287-4	chloramphenicol	0.01-0.1%

· **Additional information**
Contains human sourced and/or potentially infectious components.
Contains added constituents of animal origin.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant

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· **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
57-13-6 urea	
WEEL (United States)	Long-term value: 10 mg/m³
56-75-7 chloramphenicol	
WEEL (United States)	Long-term value: 0.5 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
Follow the usual biosafety practices for handling potentially infectious materials.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
Form: Solid
Color: Amber
· **Odor:** Light

· **pH-value at 20 °C:** 7.40 - 7.90

· **Change in condition**
Melting point/Melting range: undetermined
Boiling point/Boiling range: undetermined

· **Flash point:** Not applicable

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with**
Water: Soluble

· **Solvent content:**
Organic solvents: 0.0 %

Solids content: 100.0 %
· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values for hazardous components per OSHA criteria:**

Proprietary Reagent KF

Oral	LD50	15900 mg/kg (rat)

· **Primary irritant effect:**
· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.

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· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3
56-75-7	chloramphenicol	2A
58-08-2	caffeine	3

· **NTP (National Toxicology Program)**		
630-93-3	Phenytoin Sodium	R
56-75-7	chloramphenicol	R
57-83-0	progesterone	R

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

· **UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
20830-75-5	digoxin

· **Section 313 (40CFR372.65):**	
554-13-2	lithium carbonate

· **TSCA (Toxic Substances Control Act):**	
	Proprietary Reagent KK
614-39-1	Procainamide hydrochloride
	Proprietary Reagent KF
69-72-7	Salicylic acid
7647-14-5	sodium chloride
57-13-6	urea
7447-40-7	potassium chloride
7558-79-4	disodium hydrogenorthophosphate
103-90-2	paracetamol
554-13-2	lithium carbonate
69-93-2	uric acid
58-55-9	theophylline
630-93-3	Phenytoin Sodium
56-75-7	chloramphenicol
58-08-2	caffeine

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· **California Proposition 65:**

· **Chemicals known to cause cancer:**	
50-06-6	phenobarbital
630-93-3	Phenytoin Sodium
50-28-2	estradiol
57-83-0	progesterone
58-22-0	testosterone

· **Developmental Toxicity**	
554-13-2	lithium carbonate
298-46-4	Carbamazepin
1405-41-0	Gentamicin Sulfate
32986-56-4	tobramycin

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**		
57-13-6	urea	II

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 05/26/2015 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)

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LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
· **** Data compared to the previous version altered.***

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name ISE Low Serum Standard

Part Number AUH1014

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 CLP/GHS**

Hazardous Ingredients

Formaldehyde

Pictogram

None

Signal Word

None

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Section 2 Hazards (Continued)

2.3 Other hazards

Hazard Statements

EUH208 May produce an allergic reaction.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	< 0.1	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Muta. 2, H341 Skin Corr. 1B, H314 Skin Sens. 1, H317	15, 8

15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

Formaldehyde CAS # 50-00-0	0.75 ppm TWA; 2 ppm STEL (see 29 CFR 1910.1048)

ACGIH

Formaldehyde CAS # 50-00-0	0.3 ppm STEL; 0.1 ppm TWA

DFG MAK

Formaldehyde CAS # 50-00-0	0.6 ppm Peak (no irritation should occur during mixed exposure); 0.74 mg/m3 Peak (no irritation should occur during mixed exposure); 0.3 ppm TWA MAK; 0.37 mg/m3 TWA MAK (no irritation should occur during mixed exposure)

Ireland

Formaldehyde CAS # 50-00-0	0.2 ppm TWA; 0.4 ppm STEL

IOELVs None established

NIOSH

Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA

Japan

Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Formaldehyde CAS # 50-00-0	0.3 ppm TLV; 0.37 mg/m3 TLV; 0.6 ppm Binding STEL; 0.74 mg/m3 Binding STEL; Skin notation

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

pH	Not determined	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formaldehyde 0.027 ppm odor threshold value (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Formaldehyde CAS # 50-00-0	Dermal LD50 Rabbit 270 mg/kg; Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 100 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.	
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Formaldehyde CAS # 50-00-0	96 h LC50 Pimephales promelas: 22.6 - 25.7 mg/L -through]; 96 h LC50 Lepomis macrochirus: 1510 µg/L [static]; 96 h LC50 Brachydanio rerio: 41 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 0.032 - 0.226 mL/L -through]; 96 h LC50 Oncorhynchus mykiss: 100 - 136 mg/L [static]; 96 h LC50 Pimephales promelas: 23.2 - 29.7 mg/L [static]
Microtox	No information available.

Water Flea

Formaldehyde CAS # 50-00-0	48 h LC50 Daphnia magna: 2 mg/L; 48 h EC50 Daphnia magna: 11.3 - 18 mg/L [Static]
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 50-00-0	Formaldehyde	0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 50-00-0	Formaldehyde

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Section 15 Regulatory Information (Continued)

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 50-00-0 Formaldehyde

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7757-82-6 Sodium Sulfate
CAS # 50-00-0 Formaldehyde

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 50-00-0 Formaldehyde

Pennsylvania Right To Know (RTK) List

CAS # 7757-82-6 Sodium Sulfate
CAS # 50-00-0 Formaldehyde

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.

Updated Section 4, 8, 9, 11 - 16.

Updated Section 5.

Document version and issue/revision date

Revision Date (year/month/day) 2019/04/01
Last Revision Date (year/month/day) 2015/03/20
Document ID: AUH1014-75
Version: 04

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods

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ISE Low Serum Standard

Section 16 Other Information (Continued)

IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Document ID: DR0070-1-75: Version AE
Revision Date (year/month/day) 2018/10/05
Last Revision Date (year/month/day) 2015/11/10

Product Information

Product Name	Lyophilized Chemistry Calibrator Level 1
Part Number	DR0070-1
Series Name	AU US

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Lyophilized Chemistry Calibrator Level 1
Beckman Coulter Calibrator Diluent

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: DR0070-1-75 Version AE
Revision Date (year/month/day) 2018/10/05
Last Revision Date (year/month/day) 2015/11/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Lyophilized Chemistry Calibrator Level 1

Part Number Component of P/N DR0070-1

Series Name AU US

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.
Data given is for reconstituted solution.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Light yellow; Clear; Lyophilized - Liquid after reconstitution.; Slight odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Lyophilized Chemistry Calibrator Level 1
Lyophilized Chemistry Calibrator Level 1

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Section 2 Hazards (Continued)

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Lyophilized Chemistry Calibrator Level 1
Lyophilized Chemistry Calibrator Level 1

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Section 5 Fire Fighting Measures (Continued)

5.3	**Advice for Protective Equipment**	Self-contained breathing apparatus is recommended for in all chemical situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions	This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
6.2 Environmental Precautions	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures	If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations. If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.
6.4 Reference to other sections	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling	This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established
Sweden (AFS 2015:7 and amendments)	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized - Liquid after reconstitution.	**Gravity (Water=1.0)**	≈ 1.0
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.0 - 8.5	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Lyophilized Chemistry Calibrator Level 1
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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated Section 4.
Updated Section 8.
Updated Section 11.
Updated Section 14.
Updated Section 15.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2018/10/05
Last Revision Date (year/month/day) 2015/11/10
Document ID: DR0070-1-75
Version: AE

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Lyophilized Chemistry Calibrator Level 1
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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Last Revision Date (year/month/day) 2015/11/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Beckman Coulter Calibrator Diluent

Part Number Component of P/N DR0070-1

Series Name AU US

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation Not applicable

Eye Contact Not applicable

Skin Contact Not applicable

Ingestion Not applicable

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media Not applicable

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Not applicable

5.4 Additional information No further relevant information available.

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Section 6 Accidental Release Measures

6.1	**Personal precautions, protective equipment and emergency procedures**	
	Personal Precautions	No special precautions are necessary. Use good laboratory procedures.
6.2	**Environmental Precautions**	Contain spill to prevent migration.
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	No special precautions are necessary; use good laboratory procedures.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1	**Control parameters**	
	Exposure Limits	
	US OSHA	None established
	ACGIH	None established
	DFG MAK	None established
	Ireland	None established
	IOELVs	None established
	NIOSH	None established
	Japan	None established
	Sweden (AFS 2015:7 and amendments)	
		None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.00 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.8 - 8.6	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical Stability	The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions	No further relevant information available.
10.4 Conditions to Avoid	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5 Incompatible materials	No further relevant information available.

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Lyophilized Chemistry Calibrator Level 1
Beckman Coulter Calibrator Diluent

Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

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Section 12 Ecological Information (Continued)

12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
13.2	**Additional information**	No further relevant information available.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 0** **Reactivity with Water: 0** **Physical Contact: 0**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated Section 8. Updated Section 11. Updated Section 14.	

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BECKMAN COULTER
Lyophilized Chemistry Calibrator Level 1
Beckman Coulter Calibrator Diluent

SAFETY DATA SHEET
Document ID: DR0070-1-75 Version AE
Revision Date (year/month/day) 2018/10/05
Last Revision Date (year/month/day) 2015/11/10

Section 16 Other Information (Continued)

Updated Section 15.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2018/10/05
Last Revision Date (year/month/day) 2015/11/10
Document ID: DR0070-1-75
Version: AE

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Kit SDS Cover Sheet

Document ID: DR0070-2-75: Version AE
Revision Date (year/month/day) 2018/06/29
Last Revision Date (year/month/day) 2015/11/10

Product Information

Product Name	Lyophilized Chemistry Calibrator Level 2
Part Number	DR0070-2
Series Name	AU US

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Lyophilized Chemistry Calibrator Level 2
Beckman Coulter Calibrator Diluent

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: DR0070-2-75 Version AE
Revision Date (year/month/day) 2018/06/29
Last Revision Date (year/month/day) 2015/11/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Lyophilized Chemistry Calibrator Level 2

Part Number Component of P/N DR0070-2

Series Name AU US

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.
Data given is for reconstituted solution.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Light yellow; Clear; Lyophilized - Liquid after reconstitution.; Slight odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Lyophilized Chemistry Calibrator Level 2
Lyophilized Chemistry Calibrator Level 2

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Last Revision Date (year/month/day) 2015/11/10

Section 2 Hazards (Continued)

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Lyophilized Chemistry Calibrator Level 2
Lyophilized Chemistry Calibrator Level 2

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Last Revision Date (year/month/day) 2015/11/10

Section 5 Fire Fighting Measures (Continued)

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.

If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established
Sweden (AFS 2015:7 and amendments)	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized - Liquid after reconstitution.	**Gravity (Water=1.0)**	≈ 1.0
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Slight odor	**Organic**	Not determined
pH	7.0 - 8.5	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Lyophilized Chemistry Calibrator Level 2
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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated Section 4.
Updated Section 6.
Updated Section 8.
Updated Section 11.
Updated Section 14.
Updated Section 15.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2018/06/29
Last Revision Date (year/month/day) 2015/11/10
Document ID: DR0070-2-75
Version: AE

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BECKMAN COULTER
Lyophilized Chemistry Calibrator Level 2
Lyophilized Chemistry Calibrator Level 2

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Revision Date (year/month/day) 2018/06/29
Last Revision Date (year/month/day) 2015/11/10

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Beckman Coulter Calibrator Diluent

Part Number Component of P/N DR0070-2

Series Name AU US

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation Not applicable

Eye Contact Not applicable

Skin Contact Not applicable

Ingestion Not applicable

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media Not applicable

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Not applicable

5.4 Additional information No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions	No special precautions are necessary. Use good laboratory procedures.

6.2	**Environmental Precautions**	Contain spill to prevent migration.
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	No special precautions are necessary; use good laboratory procedures.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**end uses**	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

Sweden (AFS 2015:7 and amendments)

None established

8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.00 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.8 - 8.6	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical Stability	The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions	No further relevant information available.
10.4 Conditions to Avoid	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5 Incompatible materials	No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

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Section 12 Ecological Information (Continued)

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

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Section 15 Regulatory Information (Continued)

No ingredients listed.

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 0** **Reactivity with Water: 0** **Physical Contact: 0**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated Section 8.
Updated Section 11.
Updated Section 13.
Updated Section 14.
Updated Section 15.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2018/06/29
Last Revision Date (year/month/day) 2015/11/10
Document ID: DR0070-2-75
Version: AE

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System

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BECKMAN COULTER

Lyophilized Chemistry Calibrator Level 2
Beckman Coulter Calibrator Diluent

SAFETY DATA SHEET

Document ID: DR0070-2-75 Version AE
Revision Date (year/month/day) 2018/06/29
Last Revision Date (year/month/day) 2015/11/10

Section 16 Other Information (Continued)

vPvB - Very persistent and very bioaccumulative substances

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/01/2015

1 Identification

· **Product identifier**

· **Trade name: Lyphochek® Diabetes Control**

· **Catalog or product number:** 740, 740X
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Inhalation
Skin
Ingestion
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**	
Human Red Cells	50-100%

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/01/2015

Trade name: Lyphochek® Diabetes Control

(Contd. of page 1)

Proprietary Reagent FF	35-50%
Proprietary Reagent GG	.001-.01%

· **Additional information** Contains human sourced and/or potentially infectious components.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** Eye irritation
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
· **Reference to other sections** See Section 13 for disposal information.

*
7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/01/2015

Trade name: Lyphochek® Diabetes Control

(Contd. of page 2)

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
Proprietary Reagent GG	
PEL (United States)	Long-term value: 5 mg/m³ as CN; Skin

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
Form: Solid
Color: Red
· **Odor:** Light

· **pH-value at 20 °C:** 7.95 8.05

· **Change in condition**
Melting point/Melting range: undetermined

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/01/2015

Trade name: Lyphochek® Diabetes Control

(Contd. of page 3)

Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Not determined.
· **Density:**	Not determined
· **Solubility in / Miscibility with Water:**	Soluble
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	100.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

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Safety Data Sheet
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Trade name: Lyphochek® Diabetes Control

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12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/01/2015

Trade name: Lyphochek® Diabetes Control

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· **UN "Model Regulation":** -

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
Proprietary Reagent GG

· **Section 313 (40CFR372.65):**
Proprietary Reagent GG

· **TSCA (Toxic Substances Control Act):**
Proprietary Reagent FF
Proprietary Reagent GG

· **California Proposition 65:**

· **Developmental Toxicity**
Proprietary Reagent J7
Proprietary Reagent J15

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 05/26/2015 / -

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 *Reviewed on 05/01/2015*

Trade name: Lyphochek® Diabetes Control

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· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
· *** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

1 Identification

· **Product identifier**

· **Trade name: Lyphochek® Hemoglobin A1C Linearity Set**

· **Catalog or product number:** 12000070
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**	
Human Red Cells	50-100%

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

Trade name: Lyphochek® Hemoglobin A1C Linearity Set

(Contd. of page 1)

Proprietary Reagent FF	35-50%
Proprietary Reagent GG	.001-.01%

· **Additional information** Contains human sourced and/or potentially infectious components.

4 First-aid measures

· **Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Keep contaminated washing water and dispose of appropriately.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
· **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

Trade name: Lyphochek® Hemoglobin A1C Linearity Set

(Contd. of page 2)

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
Proprietary Reagent GG	
PEL (United States)	Long-term value: 5 mg/m³ as CN; Skin

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
Form: Solid
Color: Red
· **Odor:** Odorless

· **pH-value at 20 °C:** 7.6-8.1

· **Change in condition**
Melting point/Melting range: undetermined

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 *Reviewed on 05/26/2015*

Trade name: Lyphochek® Hemoglobin A1C Linearity Set

(Contd. of page 3)

Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with Water:**	Soluble
· **Solvent content:** **Organic solvents:**	0.0 %
Solids content:	100.0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Lyphochek® Hemoglobin A1C Linearity Set

(Contd. of page 4)

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*

14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

Trade name: Lyphochek® Hemoglobin A1C Linearity Set

(Contd. of page 5)

· **UN "Model Regulation":** -

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
Proprietary Reagent GG

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
Proprietary Reagent FF
Proprietary Chemical CP2
Proprietary Reagent GG

· **California Proposition 65:**

· **Developmental Toxicity**
Proprietary Reagent J15
Proprietary Reagent J7

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

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acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

Trade name: Lyphochek® Hemoglobin A1C Linearity Set

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· **Date of preparation / last revision** 05/26/2015 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)

· *** Data compared to the previous version altered.**

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

1 Identification

· **Product identifier**

· **Trade name: Lyphochek® Immunology Plus Control**

· **Catalog or product number:** 430, 430X
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use** SU20 Health services
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200

· **Information department:** Technical services, customer support
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Emergency overview:**
· **Routes of exposure:**
Ingestion
Inhalation
Skin
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
· **Special Hazards** Contains human sourced and/or potentially infectious components.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

EINECS: 268-338-3	Human Source Material	50-100%

(Contd. on page 2)

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acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

Trade name: Lyphochek® Immunology Plus Control

(Contd. of page 1)

	Proprietary Reagent KA	35-50%
	Proprietary Chemical CP3	5-10%
	Proprietary Reagent BS 8	2.5-5%

· **Additional information**
Contains human sourced and/or potentially infectious components.
Contains added constituents of animal origin.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** Eye irritation
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
· **Environmental precautions:**
Keep contaminated washing water and dispose of appropriately.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
· **Reference to other sections** See Section 13 for disposal information.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015 Reviewed on 05/26/2015

Trade name: Lyphochek® Immunology Plus Control

(Contd. of page 2)

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Solid
Color:	Amber
· **Odor:**	Light

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

(Contd. of page 3)

· **pH-value at 20 °C:**	6.9 - 8.30
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined
· **Solubility in / Miscibility with Water:**	Soluble
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	100.0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**	
Proprietary Reagent KB	2A

· **NTP (National Toxicology Program)**	
Proprietary Reagent KB	R

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Trade name: Lyphochek® Immunology Plus Control

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· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No

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Safety Data Sheet
acc. to OSHA HCS

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Trade name: Lyphochek® Immunology Plus Control

(Contd. of page 5)

· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	-

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
Proprietary Chemical CP3
Proprietary Reagent BS 8
Proprietary Reagent KB

· **California Proposition 65:**

· **Developmental Toxicity**
Proprietary Reagent J15

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

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Trade name: Lyphochek® Immunology Plus Control

(Contd. of page 6)

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Date of preparation / last revision** *05/26/2015 / -*

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)

· **** Data compared to the previous version altered.***

BECKMAN COULTER
Magnesium

SAFETY DATA SHEET

Document ID: OSR6189-75 Version 06
Revision Date (year/month/day) 2018/08/23
Last Revision Date (year/month/day) 2016/10/21

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name **Magnesium**

Part Number OSR6189

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Dark Blue; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

Toxic to Reproductive Category 1

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Section 2 Hazards (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

N,N-Dimethylformamide

Aminocaproic Acid

Tris(hydroxymethyl)– aminomethane

Pictogram

Signal Word

DANGER

Hazard Statements

H316 Causes mild skin irritation.

H360 May damage fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing and eye/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Aminocaproic Acid CAS # 60-32-2 EINECS # 200-469-3 Index # Not available	5 - 8	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	

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Section 3 Composition and Information on Ingredients (Continued)

Tris(hydroxymethyl)– aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
N,N-Dimethylformamide CAS # 68-12-2 EINECS # 200-679-5 Index # 616-001-00-X	0.1 - 0.2	Acute Tox. Dermal 4, H312 Acute Tox. Inhal. 4, H332 Eye Irrit. 2, H319 Flam. Liq. 3, H226 Repr. 1B, H360	Acute Tox. Dermal 4, H312 Acute Tox. Inhal. 4, H332 Eye Irrit. 2, H319 Flam. Liq. 3, H226 Repr. 1B, H360	SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.
May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

N,N-Dimethylformamide CAS # 68-12-2	10 ppm TWA; 30 mg/m3 TWA; prevent or reduce skin absorption

ACGIH

N,N-Dimethylformamide CAS # 68-12-2	5 ppm TWA; Skin - potential contribution to overall exposure by the cutaneous route
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

N,N-Dimethylformamide CAS # 68-12-2	skin notation; 10 ppm Peak; 30 mg/m3 Peak; 5 ppm TWA MAK; 15 mg/m3 TWA MAK
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

N,N-Dimethylformamide CAS # 68-12-2	5 ppm TWA; 15 mg/m3 TWA; 10 ppm STEL; 30 mg/m3 STEL; Potential for cutaneous absorption
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

N,N-Dimethylformamide CAS # 68-12-2	Possibility of uptake through the skin; 5 ppm TWA; 15 mg/m3 TWA; 10 ppm STEL; 30 mg/m3 STEL
Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

N,N-Dimethylformamide CAS # 68-12-2	500 ppm IDLH; 10 ppm TWA; 30 mg/m3 TWA

Japan

N,N-Dimethylformamide CAS # 68-12-2	10 ppm OEL; 30 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

N,N-Dimethylformamide CAS # 68-12-2	5 ppm TLV; 15 mg/m3 TLV; 10 ppm Binding STEL; 30 mg/m3 Binding STEL; Skin notation
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Dark Blue	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	11.4 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not determined
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	N,N-Dimethylformamide 0.047 ppm odor threshold value		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

N,N-Dimethylformamide CAS # 68-12-2	Dermal LD50 Rat 1100 mg/kg; Oral LD50 Rat 2800 mg/kg
Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity

Not based on available data.

Skin Corrosion/Irritation

Causes mild skin irritation.

Serious eye damage/eye irritation

Not based on available data.

Respiratory/skin sensitization

Not based on available data.

Carcinogenicity

This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not based on available data.

Reproductive Toxicity

May damage fertility or the unborn child.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard

Not based on available data.

Other Information

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

N,N-Dimethylformamide CAS # 68-12-2	96 h LC50 Lepomis macrochirus: 6300 mg/L; 96 h LC50 Oncorhynchus mykiss: 9800 mg/L -through]; 96 h LC50 Pimephales promelas: 10410 mg/L -through]
Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.

Water Flea

N,N-Dimethylformamide CAS # 68-12-2	48 h EC50 Daphnia magna: 7500 mg/L; 48 h EC50 Daphnia magna: 8485 mg/L [semi-static]; 48 h EC50 Daphnia magna: 6800 - 13900 mg/L [Static]

Fresh Water Algae

N,N-Dimethylformamide CAS # 68-12-2	96 h EC50 Desmodesmus subspicatus: >500 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 68-12-2	N,N-Dimethylformamide	1.0% de minimis concentration
CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 68-12-2	N,N-Dimethylformamide
CAS # 1310-58-3	Potassium Hydroxide
CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 68-12-2	N,N-Dimethylformamide

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

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SAFETY DATA SHEET

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Section 15 Regulatory Information (Continued)

Massachusetts Right To Know (RTK) List

CAS # 68-12-2	N,N-Dimethylformamide
CAS # 1310-58-3	Potassium Hydroxide
CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 68-12-2	N,N-Dimethylformamide
CAS # 1310-58-3	Potassium Hydroxide
CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 68-12-2	N,N-Dimethylformamide
CAS # 1310-58-3	Potassium Hydroxide
CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated Section 15 Regulatory Information.
Updated Section 2, 6, 11.
Updated Section 8.

Document version and issue/revision date

Revision Date (year/month/day) 2018/08/23
Last Revision Date (year/month/day) 2016/10/21
Document ID: OSR6189-75

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Section 16 Other Information (Continued)

Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 4 - Acute Toxicity Dermal, Category 4
Acute Tox. Inhal. 4 - Acute Toxicity Inhalation, Category 4
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Flam. Liq. 3 - Flammable Liquids, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
Repr. 1B - Toxic to Reproductive Category 1B
H226 - Flammable liquid and vapour.
H300 - Fatal if swallowed.
H312 - Harmful in contact with skin.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H332 - Harmful if inhaled.
H335 - May cause respiratory irritation.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System

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Section 16 Other Information (Continued)

vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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McKESSON

SDS DATE: 12/05/2017

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Consult Influenza A&B

MFR #: 181-36025 and 181-36026

INTENDED USE: McKesson Consult Influenza A&B is an *in vitro* rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of Influenza A and B viral infections.

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, VA 23233

INFORMATION LINE: 1-800-777-4908 Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company) Day or Night

SECTION 2: HAZARDOUS INGREDIENTS

For *in vitro* diagnostic use only. Each test strip/device is for single use only.
2.1 Avoid direct contact with chemical components. Any component containing biological material should be handled as being potentially hazardous.
2.2 All patient specimens and samples used for this test should be handled as potential infectious materials. Follow **Universal Precautions** as necessary

SECTION 3: COMPOSITION

Test Kit Components: Test strip/device, Extraction Reagent, Positive Control Swab, Negative Control Swab, Sterile Swabs.
Hazardous Substances: This product does not contain any hazardous substances above 1% or above 0.1% levels required, depending on the hazard.

Chemical	CAS#	EC#	Kit Component	Concentration	Classification	Risk Phrases
N/A	N/A	N/A	N/A	N/A	N/A	N/A

SECTION 4: FIRST AID MEASURES

Skin Contact: Immediately wash affected area with soap and water for 15 minutes. Remove and wash any contaminated clothing. If pain, irritation, or a rash occur, seek medical attention.
Eye Contact: Immediately flush eyes with water for at least 15 minutes. If pain or irritation occur, seek medical attention.
Ingestion: If swallowed, rinse mouth with copious amount of water. Do not induce vomiting. If irritation or discomfort occur, seek medical attention.
Inhalation: Move to fresh air if inhaled. If breathing becomes difficult or stops, seek medical attention immediately.

SECTION 5: FIRE & EXPLOSION HAZARD DATA

Suitable Extinguishing Media: Dry chemical, carbon dioxide, water, or foam.
Specific Hazards: Fire may cause material to produce noxious fumes or gases.

Fire Fighting Procedure: Wear self-contained breathing apparatus and protective equipment. Remove containers from fire area if possible. Cool fire-exposed containers with water.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: Kit contains material of biological origin, avoid direct contact with material. Wear protective clothing as outlined in Section 8.
Environmental Precaution: Keep away from drains, surface and ground water, and soil. Collect spilled and contaminated material in appropriate containers and dispose according to waste regulations.
Methods and Materials for Clean up: Isolate spill area to prevent further spreading of spilled material. Use absorbent so soak up spilled material. Use 10% sodium hypochlorite, 70% ethanol, or equivalent solution to clean contaminated surfaces when spilled material is of biological origin.

SECTION 7: HANDLING & STORAGE

Handling: Avoid direct contact with contents. Wear personal protective equipment (Section 8). Wash thoroughly after handling.
Storage: Store according to directions listed in the package insert. Keep away from combustible materials and ignition sources.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits: Not Available
Occupational Exposure Controls:
Engineering Controls: No special engineering controls are required.
Personal Protective Equipment:
Respiratory Protection: None needed under normal circumstances.
Hand Protection: Medical gloves (latex, nitrile, or equivalent), should be worn to avoid direct contact.
Eye Protection: Wear suitable lab safety glasses.
Skin Protection: Wear lab coat or other protective clothing.
Environmental Controls: No special environmental controls required.

SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

General Information and Important health, safety and environmental information:

Properties:	**Test Strip**	**Extraction Reagent**	**Positive Control Swab**	**Negative Control Swab**
Appearance	White strip in plastic housing	Clear, colorless liquid	White Swab	White Swab
Odor	Odorless	Odorless	Odorless	Odorless
pH	N/A	7.2	N/A	N/A
Boiling Point (°C)	N/A	N/A	N/A	N/A
Flash Point	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A
Explosive Properties	N/A	N/A	N/A	N/A
Oxidizing Properties	N/A	N/A	N/A	N/A

Vapor Pressure	N/A	N/A	N/A	N/A
Relative Density	N/A	N/A	N/A	N/A
Solubilit(ies)	Insoluble	Soluble	Swab: Insoluble Control: Soluble	Swab: Insoluble Control: Soluble
Partition coefficient: n-octanol/water	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A
Vapor Density	N/A	N/A	N/A	N/A
Evaporation Rate	N/A	N/A	N/A	N/A

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under normal conditions. Hazardous reactions are not expected to occur.
Conditions to Avoid: None identified.
Materials to avoid: None Identified.
Hazardous decomposition products: Decomposition as a result of high heat/fire may result in noxious fumes, CO and CO2.

SECTION 11: TOXICOLOGICAL INFORMATION

Presently no toxicological data available for this kit or its components.
Routes of Exposure:
Inhalation: May cause irritation of the respiratory tract.
Ingestion: May cause irritation of mouth, throat, and gastrointestinal system.
Skin Contact: May cause irritation of the skin.
Eye Contact: May cause irritation of the eyes.
Effects of Short and Long Term Exposure: No data available

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data available.
Mobility: No data available.
Persistence and degradability: No data available.
Bioaccumalitive potential: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose according to local, state, and national regulations.

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport.
UN Number: N/A
Class: N/A
Proper Shipping Name: N/A
Packing Group: N/A
Environmental Hazards: N/A

SECTION 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture: This product and its contents are not classified as dangerous under any regulation.
15.2 Chemical Safety Assessment: No Chemical Safety Assessment has been carried out on the components of this product.

SECTION 16: OTHER INFORMATION

This product is intended for *in vitro* medical diagnostic use. The tests should only be used according to the instructions provided within the kit.

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

SDS DATE: 10/29/15

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Hydrogen Peroxide, 3%
MFR #: 23-A0013, 23-D0012, 23-F0010

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company)
Day or night

PRODUCT DESCRIPTION: McKesson Hydrogen Peroxide, 3%

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: N/A

POTENTIAL HEALTH EFFECTS:

EYES: Eye Dam. 1;H318 Causes serious eye damage.

SKIN: Skin Corr. 1B;H314 Causes severe skin burns and eye damage.

INGESTION: N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY
OSHA: TWA 1 ppm (1.4mg/m3) ACGIH: TWA: 1ppm NTP: N/A IARC: N/A
OTHER: NIOSH: TWA 1ppm (1.4mg/m3)

SECTION 2 NOTES:

CAS No.	Ingredient	Source	Value
0007722-84-1	Hydrogen peroxide	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group **2b:** No; Group 3: Yes; Group 4: No;

McKESSON

SDS DATE: 10/29/15

Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.
001 - Hydrogen Peroxide 3% USP

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

[Prevention]:

P260 Do not breathe mist / vapors / spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

[Response]:

P301+330+331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Stay at rest.

P303+361+353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.

P304+340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.

P310 Immediately call a POISON CENTER or doctor / physician.

P363 Wash contaminated clothing before reuse.

[Storage]:

P405 Store locked up.

[Disposal]:

P501 Dispose of contents / container in accordance with local / national regulations.

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits

SECTION 3 NOTES:

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Hydrogen peroxide **CAS Number: 0007722-84-1**	**1.0 - 10**	**Ox. Liq. 1;H271** **Acute Tox. 4;H332** **Acute Tox. 4;H302** **Skin Corr. 1A;H314**	**[1][2]**

Substance classified with a health or environmental hazard.
Substance with a workplace exposure limit.
PBT-substance or vPVP-substance.
*The full text of the phrases are shown in Section 16.

SECTION 4: FIRST-AID MEASURES

EYES: Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

SKIN: Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

INGESTION: If swallowed do NOT induce vomiting and obtain immediate medical attention.

INHALATION: Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration.

If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Overview	Inhalation of vapors and mists irritate the nose and throat. Minimally irritating to the eyes and mildly irritating to the skin. See section 2 for further details.
Eyes	Causes serious eye damage.
Skin	Causes severe skin burns and eye damage.

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: N/A
(% BY VOLUME) LOWER: N/A

FLASH POINT: N/A
METHOD USED: N/A

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

HEALTH:	N/A	**FLAMMABILITY:**	N/A	**REACTIVITY:**	N/A	**OTHER:**	N/A

HMIS HAZARD CLASSIFICATION

HEALTH:	N/A	**FLAMMABILITY:**	N/A	**REACTIVITY:**	N/A	**PERSONAL:**	N/A

EXTINGUISHING MEDIA: Recommended extinguishing media: flood with water spray or water fog.

SPECIAL FIRE FIGHTING PROCEDURES: Do not breathe mist/vapors/spray.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: Oxygen which supports combustion.

SECTION 5 NOTES: Firefighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: N/A

SECTION 6 NOTES:
Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

Environmental precautions

Biodegradable, non-hazardous to environment.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing before reuse.

Methods and material for containment and cleaning up.

Flush with water: wear fubber boots, rubber apron and goggles.

SECTION 7: HANDLING AND STORAGE

HANDLING: See section 2 for further details. - [Prevention]:

STORAGE: Handle containers carefully to prevent damage and spillage.

Incompatible materials: Reducing agents, combustible materials.

Store in a cool, dark place. Avoid extreme heat.

See section 2 for further details. - [Storage]:

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: N/A

VENTILATION:

RESPIRATORY PROTECTION: If workers are exposed to concentrations above the exposure limit they must use the appropriate, certified respirators.

EYE PROTECTION: Protective goggles if desired.

SKIN PROTECTION: Rubber or vinyl gloves.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove solied clothing and wash thoroughly before reuse.

EXPOSURE GUIDELINES:

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Clear, colorless, odorless liquid

PHYSICAL STATE: N/A

pH AS SUPPLIED: N/A
pH (Other): N/A
BOILING POINT: 212°F
MELTING POINT: N/A
FREEZING POINT: N/A
VAPOR PRESSURE (mmHg): 23
@ N/A
DENSITY (lb/gal): N/A
@ N/A
SPECIFIC GRAVITY (H2O = 1): 1.1

@ N/A
EVAPORATION RATE: >1

BASIS (=1): N/A

SOLUBILITY IN WATER: Complete

PERCENT SOLIDS BY WEIGHT: N/A

PERCENT VOLATILE: N/A
BY WT/ N/A **BY VOL @** N/A

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

WITH WATER: N/A **LBS/GAL**
WITHOUT WATER: N/A **LBS/GAL**

MOLECULAR WEIGHT: N/A

VISCOSITY: N/A

SECTION 9 NOTES:
Heavy Metals: 5 ppm maximum
Limit of Preservative: NMT 50 mg
Hydrogen Peroxide Assay: 2.5-3.5%

SECTION 10: STABILITY AND REACTIVITY

STABLE **UNSTABLE**

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID (STABILITY): Extreme heat and combustion.

INCOMPATIBILITY (MATERIAL TO AVOID): Reducing agents, combustible materials.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Oxygen, which supports combustion.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Acute Toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LD50, mg/L/4hr	Inhalation Dust/Mist LD50, mg/L/4hr	Inhalation Gas LD50, ppm
Hydrogen peroxide - (7722-84-1)	801.00, Rat - Category: 4	2,000.00, Rat - Category: 4	2.00, Rat - Category: 2	No data available	No data available

Note: When no toute specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	1B	Causes severe skin burns and eye damage.
Serious eye damage/irritation	1	Causes serious eye damage.
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

Toxicity : No additional information provided for this product. See section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Hydrogen peroxide - (7722-84-1)	22.00, Oncorhynchus mykiss	**2.32,** Daphnia magna	0.71 (72 hr), Microcystis pulverea **ssp.** incerta

Persistence and degradability

There is no data available on the preparation itself.

Bioaccumulative potential

Not Measured

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

Other adverse effects

No data available.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Observe all federal, state and local regulations when disposing of this substance.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: Not regulated.
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
DOT SHIPPING ID NUMBER: N/A
DOT PACKING GROUP: N/A
DOT HAZARD CLASS: N/A
DOT LABEL STATEMENT: N/A

WATER TRANSPORTATION
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

AIR TRANSPORTATION
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): All components of this material are either listed or exempt from listing on the TSCA

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A

EPCRA 301 Extremely Dangerous: Hydrogen Peroxide

SARA 311/312 HAZARD CATEGORIES: To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

SARA 313 REPORTABLE INGREDIENTS: Contains NO hazardous ingredients subject to reporting requirements of Section 313 of SARA Title II.

STATE REGULATIONS:

New Jersey RTK Substances (>1%):

Hydrogen peroxide

Pennsylvania RTK Substances (>1%):

Hydrogen peroxide

Proposition 65 - Carcinogens (>0.0%):
No chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

No chemicals at levels which require reporting under this statute.

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

HealthLink® A Family of Medical Products
Joining Forces to Serve the Healthcare Community
CLOROX HEALTHCARE®

Safety Data Sheet

Methanol

Revision Date: 6/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier Trade name: Methanol
Product code(s): 400480, 400481

1.2 Relevant identified use Laboratory Reagent

1.3 Supplier HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM

1.4 Emergency Telephone CHEMTREC 800.424.9300

2. HAZARDS IDENTIFICATION

2.2 GHS Label elements, including precautionary statements

Signal Word: Danger!

2.1 Classification of the substance or mixture

Hazard statement(s):

H225: Highly flammable liquid and vapor (Cat 2).
H315: Causes skin irritation (Cat 2)
H319: Causes serious eye irritation (Cat 2/2A).
H332: Harmful if inhaled (Cat 4).

Precautionary statement(s):

P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P260: Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P280: Wear protective gloves/ eye protection/ face protection.
P305+351+338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 WHMIS Classification

B-2 Flammable Liquid

2.4 NFPA Rating

Health hazard: 1
Fire: 3
Reactivity Hazard: 0

Target Organs

Eyes, Kidney, Liver, Heart, Central nervous system, Blood, Optic nerve

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Components	Name	CAS number	% by weight
	Methanol	67-56-1	100

4. FIRST AID MEASURES

4.1 General Information

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention immediately.

Skin contact: In case of contact, flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.

Inhalation: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.

Ingestion: Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media: Use dry chemical, CO2, water spray (fog) or foam. Not suitable, do not use water jet.

5.2 Special hazards: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

5.3 Hazardous Products: Flammable liquid. In a fire or if heated, a pressure increase will occur and the container may burst with the risk of a subsequent explosion. Run-off to sewer may create fire or explosion hazard.

5.4 Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

5.5 Special remarks on explosion hazards: Vapor may cause flash fire. Vapors may accumulate in low or confined areas or travel a considerable distance to a source of ignition and flash back.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Do not breathe vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).

6.2 Environmental precaution: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Clean up: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container.

7. HANDLING AND STORAGE

7.1 Safe Handling: Do not get in eyes, on skin or clothing. Do not breathe vapor or mist. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use non-sparking tools. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Use empty containers to retain product, residue can be hazardous. Do not reuse container.

7.2 Storage: Store in accordance with local regulations. Store in a segregated and approved area.. Store in original container, protected from direct sunlight. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters

Methanol: **Exposure limits**
ACGIH (United States, 1994). Absorbed through skin.
TWA: 262 mg/m^3
STEL: 328 mg/m^3
OSHA (United States, 1989). Absorbed through skin.
TWA: 260 mg/m^3
STEL: 325 mg/m^3
ACGIH TLV (United States, 1/2008). Absorbed through skin.
TWA: 200 ppm 8 hour(s).

TWA: 262 mg/m^3 8 hour(s).
STEL: 250 ppm 15 minute(s).
STEL: 328 mg/m^3 15 minute(s).
OSHA PEL 1989 (United States, 3/1989). Absorbed through skin.
TWA: 200 ppm 8 hour(s).
TWA: 260 mg/m^3 8 hour(s).
STEL: 250 ppm 15 minute(s).
STEL: 325 mg/m^3 15 minute(s).
NIOSH REL (United States, 6/2008). Absorbed through skin.
TWA: 200 ppm 10 hour(s).
TWA: 260 mg/m^3 10 hour(s).
STEL: 250 ppm 15 minute(s).
STEL: 325 mg/m^3 15 minute(s).
OSHA PEL (United States, 11/2006).
TWA: 200 ppm 8 hour(s).
TWA: 260 mg/m^3 8 hour(s).

8.2 Engineering measures: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

8.3 Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

8.4 Personal protection

Respiratory: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Hands: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Recommended: neoprene
Eyes: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. Recommended: splash goggles
Skin: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat

8.5 Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid.	**Color:**	Dark blue
Flash Point:	Open Cup: 15.85C (60.5F)	**Auto-ignition temperature:**	464C (867.2F)
Flammable limits:	Lower: 6%, Upper: 36.5%	**Odor:**	Characteristic, alcohol-like.
Molecular Weight:	32.05 g/mole	**Molecular formula:**	C-H4-O
pH:	Not available.	**Boiling/condensation point:**	64.5C (148.1F)

Melting/freezing point:		-97.8C (-144F)	**Relative density:** 0.792
Vapor pressure:	12.9 lPa (97 mm Hg)	**Vapor density:**	1.11 [Air=1]
Volatility:	100% (v/v)	**Odor threshold:**	100ppm
Evaporation rate:	2.1 (butyl acetate=1)	**VOC:**	100% (w/w)
Solubility:	Not available	**Decomposition temperature:** Not Available	

10. STABILITY AND REACTIVITY

10.1 Chemical stability: The product is stable.

10.2 Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.

10.3 Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.

10.4 Conditions to avoid: Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition

10.5 Materials to avoid: Highly reactive or incompatible with the following materials: oxidizing materials. Reactive or incompatible with the following materials: metals and acids.

10.6 Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not occur

.

10.7 Conditions of reactivity: Highly flammable in the presence of the following materials or conditions: open flames, sparks and static discharge, heat, shocks and mechanical impacts and oxidizing materials. Highly explosive in the presence of the following materials or conditions: open flames, sparks and static discharge, heat, shocks and mechanical impacts and oxidizing materials. Vapor may cause flash fire. Vapors may accumulate in low or confined areas or travel a considerable distance to a source of ignition and flash back.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity

Oral LD50:	no data available
Inhalation LC50:	no data available
Dermal LD50:	no data available
Other information on acute toxicity:	no data available
Skin corrosion/irritation:	no data available
Serious eye damage/eye irritation:	no data available
Respiratory or skin sensitization:	no data available
Germ cell mutagenicity:	no data available
Specific target organ toxicity, single exposure (Globally Harmonized System):	no data available
Specific target organ toxicity, repeated exposure (Globally Harmonized System):	no data available
Aspiration hazard:	no data available

11.2 Potential Health Effects

Inhalation: Toxic if inhaled. Causes respiratory tract irritation.
Ingestion: Toxic if swallowed.
Skin: Toxic if absorbed through skin. Causes skin irritation.
Eyes: Causes eye irritation.

11.2 Signs and Symptoms of Exposure

Warning: Contains methanol. May be fatal or cause blindness if swallowed. Cannot be made nonpoisonous. , Effects due to ingestion may include:, Gastrointestinal disturbance, Headache, Nausea, Vomiting, Dizziness, Weakness, Confusion, Drowsiness, Unconsciousness, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity Data (United States) Methanol

Species	Period	Result
Daphia Magna (EC50)	48 hour/hours	>10000 mg/l
Oncorhynchus myKiss (EC50)	48 hour/hours	13200 mg/l
Lepomis Macrochirus (EC50)	48 hour/hours	16000 mg/l
Daphia Magna (LC50)	96 hour/hours	>100 mg/l
Pimephales Promelas (LC 50)	96 hour/hours	>100 mg/l
Lepomis Macrochirus (LC50)	96 hour/hours	15400 mg/l

12.2 Environmental Precautions:

No known significant effects or critical hazardous. The products of degradation are less toxic than the product itself.

13. DISPOSAL CONSIDERATIONS

13.1 Methods: The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national, local laws and regulations.

14. TRANSPORT INFORMATION

Land Transport DOT (US)

UN No. UN1230
Proper Shipping Name **Me**thanol Solution
Hazard Class 3
Packing Group II

TDG
UN No. UN1230
Proper Shipping Name **Me**thanol Solution
Hazard Class 3
Subsidiary Hazard Class 6.1
Packing Group II

IATA
UN No. UN1230
Proper Shipping Name **Me**thanol Solution
Hazard Class 3
Subsidiary Hazard Class 6.1
Packing Group II

IMDG/IMP
UN No. UN1230
Proper Shipping Name **Me**thanol Solution
Hazard Class 3
Subsidiary Hazard Class 6.1

Packing Group II

15. REGULATORY INFORMATION

United States

HCS Classification: Flammable liquid, Highly toxic material, Irritating material, Target organ effects

U.S. Federal regulations: **TSCA 8(a) IUR**: Partial exemption
United States inventory (TSCA 8b):
Listed on inventory.
SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.
SARA 302/304/311/312 hazardous chemicals: Methanol
SARA 311/312 MSDS distribution - chemical inventory - hazard identification:
Methanol: Fire hazard, Immediate (acute) health hazard, Delayed (chronic) health hazard
Clean Water Act (CWA) 307: No products were found.
Clean Water Act (CWA) 311: No products were found.
Clean Air Act (CAA) 112 accidental release prevention: No products were found.
Clean Air Act (CAA) 112 regulated flammable substances: No products were found.
Clean Air Act (CAA) 112 regulated toxic substances: No products were found.

DEA List I & II Chemicals (Precursor Chemicals): Not listed

SARA 313

	Product name	CAS number	Concentration
Form R - Reporting Requirements:	Methanol	64-17-5	99 - 100
Supplier notification:	Methanol	64-17-5	99 - 100

SARA 313 notifications must not be detached from the MSDS and any copying and redistribution of the MSDS shall\ include copying and redistribution of the notice attached to copies of the MSDS subsequently redistributed.

RTK: Methanol, CAS 67-56-1, Listed, CT, MA, MN, MN, NJ, RI

Prop 65

WHMIS (Canada): Class B-2: Flammable Liquid
Class D-1A: Material causing immediate and serious toxic effects (Very toxic).
Class D-2B: Material causing other toxic effects (Toxic).

Canadian lists: **CEPA Toxic substances**: None of the components are listed.
Canadian ARET: None of the components are listed.
Canadian NPRI: None of the components are listed.
Alberta Designated Substances: None of the components are listed.
Ontario Designated Substances: None of the components are listed.
Quebec Designated Substances: None of the components are listed.

CEPA DSL / CEPA NDSL: All components are listed or exempted.
CERCLA: Methyl Alcohol: RQ 5000 lb

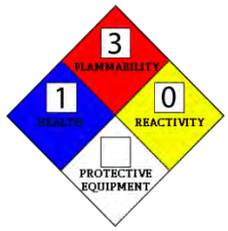
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

International regulations

International lists: **Australia inventory (AICS)**: All components are listed or exempted.
China inventory (IECSC): All components are listed or exempted.
Japan inventory: Not determined.

Korea inventory: Not determined.
New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.
Philippines inventory (PICCS): All components are listed or exempted.

16. OTHER INFORMATION



National Fire Protection Association (U.S.A.)

Disclaimer
The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Healthlink shall not be liable for any damage resulting from handling.

Kit SDS Cover Sheet

Doc. ID: OSR6167-75: Rev. 04
Revised (year/month/day) 2015/04/02

Product Information

Product Name	MICROALBUMIN
Part Number	OSR6167

Components

Description	Microalbumin R1 Microalbumin R2

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: OSR6167-75 Rev. 04
Revised (year/month/day) 2015/04/02

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Microalbumin R1

Part Number Component of P/N OSR6167

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

For full text of R- phrases: see Section 16.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Xi;R36/37/38	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Wear protective gloves, protective clothing and eye/face protection.

Observe general safety guidelines for protection; avoid eye and skin contact.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain efficacy, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	0.99977 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.6 @20°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0 °C	**Auto-ignition Temp.**	Product is not selfigniting
Boiling Point	Similar to water, approximately 100 °C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation Causes mild skin irritation.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
Xi - Irritant

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Section 16 Other Information (Continued)

R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R36/37/38 Irritating to eyes, respiratory system and skin.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: OSR6167-75 Rev. 04
Revised (year/month/day) 2015/04/02

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Microalbumin R2

Part Number Component of P/N OSR6167

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

For full text of R- phrases: see Section 16.

Light orange; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Xi;R36/37/38	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain efficacy, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

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Section 8 Exposure Controls and Personal Protection (Continued)

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	Not determined
Color	Light orange	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.6 @20°C	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0 °C	**Auto-ignition Temp.**	Product is not selfigniting
Boiling Point	Similar to water, approximately 100 °C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide
CAS # 26628-22-8: 96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
S36 Wear suitable protective clothing.
S60 This material and/or its container must be disposed of as hazardous waste.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

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Section 15 Regulatory Information (Continued)

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
Xi - Irritant
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R36/37/38 Irritating to eyes, respiratory system and skin.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association

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Section 16 Other Information (Continued)

ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Creation Date 03-Oct-2014 **Revision Date** 03-Oct-2014 **Revision Number** 1

1. Identification

Product Name **Modified Wright Stain Pack - Stain Solution**

Cat No. : **3000**

Synonyms No information available

Recommended Use Laboratory chemicals.

Uses advised against No Information available

Details of the supplier of the safety data sheet

Company
Richard Allan Scientific
A Subsidiary of Thermo Fisher Scientific
4481 Campus Drive
Kalamazoo, MI 49008
Tel: (800) 522-7270

Emergency Telephone Number
Chemtrec US: (800) 424-9300
Chemtrec EU: 001 (202) 483-7616

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable liquids	Category 2
Acute oral toxicity	Category 3
Acute dermal toxicity	Category 3
Acute Inhalation Toxicity - Vapors	Category 3
Specific target organ toxicity (single exposure)	Category 1
Target Organs - Central nervous system (CNS), Optic nerve.	
Specific target organ toxicity - (repeated exposure)	Category 1
Target Organs - Kidney, Liver, spleen.	

Label Elements

Signal Word
Danger

Hazard Statements
Highly flammable liquid and vapor
Toxic if swallowed
Toxic in contact with skin
Toxic if inhaled
May cause drowsiness or dizziness
Causes damage to organs
Causes damage to organs through prolonged or repeated exposure

Precautionary Statements
Prevention
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Wear protective gloves/protective clothing/eye protection/face protection
Use only outdoors or in a well-ventilated area
Do not breathe dust/fume/gas/mist/vapors/spray
Keep away from heat/sparks/open flames/hot surfaces. - No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof electrical/ventilating/lighting/equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Keep cool
Response
IF exposed: Call a POISON CENTER or doctor/physician
Inhalation
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
Call a POISON CENTER or doctor/physician
Skin
Call a POISON CENTER or doctor/physician if you feel unwell
Wash contaminated clothing before reuse
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
Ingestion
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth
Fire
In case of fire: Use CO2, dry chemical, or foam for extinction
Storage
Store locked up
Store in a well-ventilated place. Keep container tightly closed
Disposal
Dispose of contents/container to an approved waste disposal plant
Hazards not otherwise classified (HNOC)

Other hazards
Poison, may be fatal or cause blindness if swallowed. Vapor harmful. Cannot be made non-poisonous. WARNING! This product contains a chemical known in the State of California to cause birth defects or other reproductive harm.

3. Composition / information on ingredients

Component	CAS-No	Weight %
Methyl alcohol	67-56-1	>96
Stains, biological, Wright's	68988-92-1	<1
Ethanamine, N-ethyl-, hydrochloride	660-68-4	<1
Methylene blue trihydrate	7220-79-3	<1
Triton X-100	9002-93-1	<1

4. First-aid measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.
Inhalation	Move to fresh air. If breathing is difficult, give oxygen. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with a respiratory medical device. Immediate medical attention is required.
Ingestion	Do not induce vomiting. Call a physician or Poison Control Center immediately.
Most important symptoms/effects	Breathing difficulties. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting
Notes to Physician	Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media	CO_2, dry chemical, dry sand, alcohol-resistant foam. Cool closed containers exposed to fire with water spray.
Unsuitable Extinguishing Media	Water may be ineffective
Flash Point	12 °C / 53.6 °F
Method -	No information available
Autoignition Temperature	464 °C / 867.2 °F

Explosion Limits

Upper	36.0 vol %
Lower	6.0 vol %
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available

Specific Hazards Arising from the Chemical
Flammable. Risk of ignition. Vapors may form explosive mixtures with air. Vapors may travel to source of ignition and flash back. Containers may explode when heated.

Hazardous Combustion Products
Carbon monoxide (CO) Formaldehyde
Protective Equipment and Precautions for Firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

NFPA

Health	Flammability	Instability	Physical hazards
3	3	0	N/A

6. Accidental release measures

Personal Precautions	Use personal protective equipment. Remove all sources of ignition. Take precautionary measures against static discharges. Do not get in eyes, on skin, or on clothing.
Environmental Precautions	Should not be released into the environment. See Section 12 for additional ecological information. Do not flush into surface water or sanitary sewer system.
Methods for Containment and Clean Up	Remove all sources of ignition. Soak up with inert absorbent material. Take precautionary measures against static discharges. Keep in suitable, closed containers for disposal.

7. Handling and storage

Handling Use only under a chemical fume hood. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharges. Do not breathe vapors or spray mist. Do not get in eyes, on skin, or on clothing. Do not ingest.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition. Flammables area.

8. Exposure controls / personal protection

Exposure Guidelines

Component	ACGIH TLV	OSHA PEL	NIOSH IDLH
Methyl alcohol	TWA: 200 ppm STEL: 250 ppm Skin	(Vacated) TWA: 200 ppm (Vacated) TWA: 260 mg/m³ (Vacated) STEL: 250 ppm (Vacated) STEL: 325 mg/m³ Skin TWA: 200 ppm TWA: 260 mg/m³	IDLH: 6000 ppm TWA: 200 ppm TWA: 260 mg/m³ STEL: 250 ppm STEL: 325 mg/m³

Component	Quebec	Mexico OEL (TWA)	Ontario TWAEV
Methyl alcohol	TWA: 200 ppm TWA: 262 mg/m³ STEL: 250 ppm STEL: 328 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 250 ppm STEL: 310 mg/m³	TWA: 200 ppm STEL: 250 ppm Skin

Legend

ACGIH - American Conference of Governmental Industrial Hygienists
OSHA - Occupational Safety and Health Administration
NIOSH IDLH: The National Institute for Occupational Safety and Health Immediately Dangerous to Life or Health

Engineering Measures Use only under a chemical fume hood. Use explosion-proof electrical/ventilating/lighting/equipment. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State	Liquid
Appearance	Dark blue - Purple
Odor	Alcohol-like
Odor Threshold	No information available
pH	6 - 7
Melting Point/Range	-94 °C / -137.2 °F
Boiling Point/Range	65 °C / 149 °F
Flash Point	12 °C / 53.6 °F
Evaporation Rate	4.6 (Butyl Acetate = 1.0)
Flammability (solid,gas)	No information available
Flammability or explosive limits	
Upper	36.0 vol %
Lower	6.0 vol %
Vapor Pressure	97.25 mmHg @ 20°C
Vapor Density	1.11 (Air = 1.0)
Relative Density	0.791

Solubility	Soluble in water
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	464 °C / 867.2 °F
Decomposition temperature	No information available
Viscosity	No information available

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products. Heat, flames and sparks.

Incompatible Materials Strong oxidizing agents, Peroxides, Acids, Acid anhydrides, Acid chlorides, Metals

Hazardous Decomposition Products Carbon monoxide (CO), Formaldehyde

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information No acute toxicity information is available for this product

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Methyl alcohol	6200 mg/kg (Rat)	Not listed	22500 ppm (Rat) 8 h
Triton X-100	1800 mg/kg (Rat)	Not listed	Not listed

Toxicologically Synergistic Products No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation Irritating to eyes and skin

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
Methyl alcohol	67-56-1	Not listed	Not listed	Not listed	Not listed	Not listed
Stains, biological, Wright's	68988-92-1	Not listed	Not listed	Not listed	Not listed	Not listed
Ethanamine, N-ethyl-, hydrochloride	660-68-4	Not listed	Not listed	Not listed	Not listed	Not listed
Methylene blue trihydrate	7220-79-3	Not listed	Not listed	Not listed	Not listed	Not listed
Triton X-100	9002-93-1	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects No information available

Reproductive Effects Experiments have shown reproductive toxicity effects on laboratory animals.

Developmental Effects Developmental effects have occurred in experimental animals.

Teratogenicity Teratogenic effects have occurred in experimental animals.

STOT - single exposure Central nervous system (CNS) Optic nerve

STOT - repeated exposure Kidney Liver spleen

Aspiration hazard No information available

Symptoms / effects,both acute and delayed Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting

Endocrine Disruptor Information

Component	EU - Endocrine Disrupters Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Japan - Endocrine Disruptor Information
Triton X-100	Group III Chemical	Not applicable	Not applicable

Other Adverse Effects Tumorigenic effects have been reported in experimental animals. See actual entry in RTECS for complete information.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea
Methyl alcohol	Not listed	Pimephales promelas: LC50 > 10000 mg/L 96h	EC50 = 39000 mg/L 25 min EC50 = 40000 mg/L 15 min EC50 = 43000 mg/L 5 min	EC50 > 10000 mg/L 24h
Triton X-100	Not listed	LC50 = 8.9 mg/L 96H	Not listed	EC50 = 26 mg/L 48h

Persistence and Degradability No information available

Bioaccumulation/ Accumulation No information available.

Mobility .

Component	log Pow
Methyl alcohol	-0.74

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

Component	RCRA - U Series Wastes	RCRA - P Series Wastes
Methyl alcohol - 67-56-1	U154	-

14. Transport information

DOT

- **UN-No** UN1230
- **Proper Shipping Name** METHANOL SOLUTION
- **Hazard Class** 3
- **Packing Group** II

TDG

- **UN-No** UN1230
- **Proper Shipping Name** METHANOL SOLUTION
- **Hazard Class** 3
- **Packing Group** II

IATA

- **UN-No** UN1230
- **Proper Shipping Name** METHANOL SOLUTION
- **Hazard Class** 3
- **Packing Group** II

IMDG/IMO

- **UN-No** UN1230
- **Proper Shipping Name** METHANOL SOLUTION
- **Hazard Class** 3

Packing Group II

15. Regulatory information

All of the components in the product are on the following Inventory lists: X = listed The product is classified and labeled according to EC directives or corresponding national laws The product is classified and labeled in accordance with Directive 1999/45/EC No information available

International Inventories

Component	TSCA	DSL	NDSL	EINECS	ELINCS	NLP	PICCS	ENCS	AICS	IECSC	KECL
Methyl alcohol	X	X	-	200-659-6	-		X	X	X	X	X
Stains, biological, Wright's	X	X	-	273-541-5	-		X	-	X	X	-
Ethanamine, N-ethyl-, hydrochloride	X	X	-	211-541-9	-		X	X	X	X	X
Triton X-100	X	X	-	-	-		X	X	X	X	X

Legend:
X - Listed
E - Indicates a substance that is the subject of a Section 5(e) Consent order under TSCA.
F - Indicates a substance that is the subject of a Section 5(f) Rule under TSCA.
N - Indicates a polymeric substance containing no free-radical initiator in its inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.
P - Indicates a commenced PMN substance
R - Indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
S - Indicates a substance that is identified in a proposed or final Significant New Use Rule
T - Indicates a substance that is the subject of a Section 4 test rule under TSCA.
XU - Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(B).
Y1 - Indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.
Y2 - Indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

U.S. Federal Regulations

TSCA 12(b) Not applicable

SARA 313

Component	CAS-No	Weight %	SARA 313 - Threshold Values %
Methyl alcohol	67-56-1	>96	1.0

SARA 311/312 Hazardous Categorization

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	Yes
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act Not applicable

Clean Air Act

Component	HAPS Data	Class 1 Ozone Depletors	Class 2 Ozone Depletors
Methyl alcohol	X		-

OSHA Occupational Safety and Health Administration
Not applicable

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Component	Hazardous Substances RQs	CERCLA EHS RQs

Methyl alcohol	5000 lb	-

California Proposition 65 This product does not contain any Proposition 65 chemicals

Component	CAS-No	California Prop. 65	Prop 65 NSRL	Category
Methyl alcohol	67-56-1	Developmental	-	Developmental

State Right-to-Know

Component	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Methyl alcohol	X	X	X	X	X
Methylene blue trihydrate	-	-	-	X	-

U.S. Department of Transportation

Reportable Quantity (RQ): Y
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland Security
This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade Serious risk, Grade 3

Canada
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR

WHMIS Hazard Class
B2 Flammable liquid
D2A Very toxic materials
D1A Very toxic materials

16. Other information

Prepared By
Regulatory Affairs
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Creation Date 03-Oct-2014
Revision Date 03-Oct-2014
Print Date 03-Oct-2014
Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard replacing the current legislation under 29 CFR 1910.1200 to align with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Disclaimer
The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of SDS

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 445930-75 Rev. AG
Revised (year/month/day) 2015/05/08

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Microprotein Calibrator

Part Number 445930

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Transparent; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Acute Toxicity Oral, Category 4

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Acute Toxicity Oral, Category 4

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethylene Glycol

Pictogram

Signal Word

WARNING

Hazard Statements

H302 Harmful if swallowed.

Precautionary Statements

P264 Wash hands thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethylene Glycol CAS # 107-21-1 EINECS # 203-473-3 Index # 603-027-00-1	30 - 40	Xn;R 22	Acute Tox. Oral 4 H302	Acute Tox. Oral 4 H302	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

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Section 4 First Aid Measures (Continued)

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Avoid inhaling, ingesting, and contact with eyes and skin.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions — Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at -20 to -15°C , as directed on the product label. Keep container closed.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Ethylene Glycol
CAS # 107-21-1 — 100 mg/m3 Ceiling (aerosol only)

DFG MAK

Ethylene Glycol
CAS # 107-21-1 — 20 ppm Peak; 52 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 26 mg/m3 TWA MAK

Ireland

Ethylene Glycol
CAS # 107-21-1 — 10 mg/m3 TWA (particulate); 20 ppm TWA (vapour); 52 mg/m3 TWA (vapour); 40 ppm STEL (vapour); 104 mg/m3 STEL (vapour); Potential for cutaneous absorption

IOELVs

Ethylene Glycol
CAS # 107-21-1 — Possibility of significant uptake through the skin; 20 ppm TWA; 52 mg/m3 TWA; 40 ppm STEL; 104 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈1.06 @20°C
Color	Colorless	**Solubility**	
Transparency	Transparent	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.8-7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Ethylene Glycol CAS # 107-21-1	Oral LD50 Rat 4000 mg/kg; Dermal LD50 Rabbit 9530 µL/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information Harmful if swallowed.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Ethylene Glycol CAS # 107-21-1	96 h LC50 Oncorhynchus mykiss: 41000 mg/L; 96 h LC50 Oncorhynchus mykiss: 14 - 18 mL/L [static]; 96 h LC50 Lepomis macrochirus: 27540 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 40761 mg/L [static]; 96 h LC50 Pimephales promelas: 40000 - 60000 mg/L [static]; 96 h LC50 Poecilia reticulata: 16000 mg/L [static]
Microtox	No information available.

Water Flea

Ethylene Glycol CAS # 107-21-1	48 h EC50 Daphnia magna: 46300 mg/L

Fresh Water Algae

Ethylene Glycol CAS # 107-21-1	96 h EC50 Pseudokirchneriella subcapitata: 6500 - 13000 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Glycol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

Pennsylvania RTK

Acetaldehyde is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful

Xn

Risk and Safety Phrases

R22 Harmful if swallowed.

S37/39 Wear suitable gloves and eye/face protection.

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Section 15 Regulatory Information (Continued)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Glycol
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

Xn - Harmful
R 22 Harmful if swallowed.
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
H302 - Harmful if swallowed.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances

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Section 16 Other Information (Continued)

SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

MULTISTIX 10 SG

SIEMENS

MSDS no. 2161

Section 1. Identification

GHS product identifier : MULTISTIX 10 SG

Product code : 2161, 10336425, 2300A, 10339493

Other means of identification : Not available.

Product type : Solid.

Relevant identified uses of the substance or mixture and uses advised against

Manufactured/supplied : Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
1-847-267-5300
1-877-229-3711

(800) 424-9300 (CHEMTREC) (24/365)

Section 2. Hazards identification

OSHA/HCS status : This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : In case of fire, use water spray (fog), foam or dry chemical.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : No specific data.

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 8. Exposure controls/personal protection

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Physical state : Solid.

Color : White.

Odor : Odorless.

pH : Not applicable.

Flash point : Not available.

Flammability (solid, gas) : Not available.

Relative density : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Not available.

Irritation/Corrosion

Not available.

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Section 11. Toxicological information

Not available.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Section 12. Ecological information

Toxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

DOT Classification

UN number Not regulated.

UN proper shipping name -

Section 14. Transport information

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

TDG Classification

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

Mexico Classification

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

ADR/RID

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Section 14. Transport information

Packing group -

Environmental hazards No.

Additional information -

IMDG

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

IATA

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined
United States inventory (TSCA 8b): Not determined.
Clean Water Act (CWA) 307: arsanilic acid
Clean Water Act (CWA) 311: Iron chloride (FeCl3), hexahydrate

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

WARNING: This product contains less than 0.1% of a chemical known to the State of California to cause cancer.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
p-arsanilic acid	Yes.	No.	0.06 µg/day (inhalation)	No.

Canada inventory : Not determined.

International regulations

International lists : **Australia inventory (AICS)**: Not determined.
China inventory (IECSC): Not determined.
Japan inventory: Not determined.
Korea inventory: Not determined.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Section 15. Regulatory information

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Date of issue/Date of revision : 10/21/2014.

Version : 1

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

Indicates information that has changed from previously issued version.

Notice to reader

Allergen : **Not available.**

Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® Latex Reagent

Section 1 Identification	
Product name	OC-Auto® Latex Reagent
Catalog number	OC80, OC802, OCDL
Recommended use	Latex Reagent for use in OC-Auto testing
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	Not applicable

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains no hazardous ingredients
Chemical name	Latex suspension. Does not contain natural latex.
Synonyms	Latex beads, polystyrene
CAS number	Not applicable
Concentration	Not applicable

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 8°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	White milky liquid
Odor	Odorless
Odor threshold	Not determined
pH	7.2 – 7.6
Melting point / Freezing point	Approximately 0°C
Initial boiling point and boiling range	Approximately 100°C
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Not applicable
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Not applicable

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Not listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

OC-Auto® Latex Reagent

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards		Protective Equipment	B
Date of preparation	23 September 2014		
Last revision date	26 February 2015		
The information in this SDS is believed to be accurate and complete at the time of revision. No warranty, express or implied, is made, and Polymedco assumes no legal responsibility or liability from its use. The user of our products is responsible for observing any applicable laws and guidelines.			

Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® Buffer Solution

Section 1 Identification	
Product name	OC-Auto® Buffer Solution
Catalog number	OC80B, OCDB
Recommended use	Buffer solution for use in OC-Auto testing
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	Not applicable

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains no hazardous ingredients
Chemical name	HEPES
Synonyms	4-(2-Hydroxyethyl)piperazine-1-ethanesulfonic acid
CAS number	7365-45-9
Concentration	50 mM

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 8°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Clear colorless liquid
Odor	Odorless
Odor threshold	Not determined
pH	7.0 – 7.8
Melting point / Freezing point	Approximately 0°C
Initial boiling point and boiling range	Approximately 100°C
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Not applicable
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Not applicable

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards		Protective Equipment	B
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
The information in this SDS is believed to be accurate and complete at the time of revision. No warranty, express or implied, is made, and Polymedco assumes no legal responsibility or liability from its use. The user of our products is responsible for observing any applicable laws and guidelines.			

Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® Calibration Kit

Section 1 Identification	
Product name	OC-Auto® Calibration Kit
Catalog number	OC80C
Recommended use	Calibrator for OC-Auto Micro 80 and OC-Auto SENSOR DIANA analyzers
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	This product is derived from human source material that has been tested and found negative for Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus (HCV) antibody. FDA approved methods have been used to conduct these tests. No test can offer complete assurance that infectious agents are absent, so handle this product as potentially biohazardous material.

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains human hemoglobin
Chemical name	Human Hemoglobin
Synonyms	Not applicable
CAS number	Not applicable
Concentration	Not applicable

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill. Decontaminate spill area with bleach or other suitable disinfectant.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 8°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties		
	Calibrator	Diluent
Appearance	Slightly brown dry solid	Clear solution
Odor	Odorless	Odorless
Odor threshold	Not determined	Not determined
pH	Not available	7.0 – 9.0
Melting point / Freezing point	Not applicable	Approx. 0°C
Initial boiling point and boiling range	Not applicable	Approx. 100°C
Flash point	Not applicable	Not applicable
Evaporation rate	Not applicable	Not determined
Flammability (solid, gas)	Not determined	Not applicable
Upper/lower flammability or explosive limits	Not determined	Not applicable
Vapor pressure	Not applicable	Not determined
Vapor density	Not applicable	Not determined
Relative density	Not determined	Not determined
Solubility	Soluble in water	Soluble in water
Partition coefficient	Not determined	Not determined
Auto-ignition temperature	Not determined	Not determined
Decomposition temperature	Not determined	Not determined
Viscosity	Not determined	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Controls: Leak-proof container marked with biohazard symbol.
Disposal methods	Dispose of human source materials in biohazardous or medical waste. Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Potentially biohazardous material; dispose in biohazardous or medical waste
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Dispose in biohazardous or medical waste

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Not listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards	Potential biohazard	Protective Equipment	B
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
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Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® FOBT-CHEK® Negative Control

Section 1 Identification	
Product name	OC-Auto® FOBT-CHEK® Negative Control
Catalog number	OCQN
Recommended use	Negative Control for OC-Auto testing
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	Not applicable

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains no hazardous ingredients
Chemical name	Not applicable
Synonyms	Not applicable
CAS number	Not applicable
Concentration	Not applicable

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 8°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Clear colorless liquid
Odor	Odorless
Odor threshold	Not determined
pH	7.0 – 9.0
Melting point / Freezing point	Approximately 0°C
Initial boiling point and boiling range	Approximately 100°C
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Not applicable
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Not applicable

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Not listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards		Protective Equipment	B
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
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Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® FOBT-CHEK® Positive Control

Section 1 Identification	
Product name	OC-Auto® FOBT-CHEK® Positive Control
Catalog number	OCQP
Recommended use	Positive Control for OC-Auto testing
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	This product is derived from human source material that has been tested and found negative for Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus (HCV) antibody. FDA approved methods have been used to conduct these tests. No test can offer complete assurance that infectious agents are absent, so handle this product as potentially biohazardous material.

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains human hemoglobin
Chemical name	Human Hemoglobin
Synonyms	Not applicable
CAS number	Not applicable
Concentration	Not applicable

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill. Decontaminate spill area with bleach or other suitable disinfectant.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 8°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Slightly brown dry solid
Odor	Odorless
Odor threshold	Not determined
pH	Not available
Melting point / Freezing point	Not applicable
Initial boiling point and boiling range	Not applicable
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not determined
Vapor pressure	Not applicable
Vapor density	Not applicable
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Controls: Leak-proof container marked with biohazard symbol.
Disposal methods	Dispose of human source materials in biohazardous or medical waste. Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Potentially biohazardous material; dispose in biohazardous or medical waste
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Dispose in biohazardous or medical waste

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Not listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards	Potential biohazard	Protective Equipment	B
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
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Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® Wash Solution

Section 1 Identification	
Product name	OC-Auto® Micro 80 Wash Solution OC-Auto® SENSOR DIANA Wash Solution
Catalog number	OC80W; OCDW
Recommended use	Wash solution for OC-Auto Micro 80 AND OC-Auto SENSOR DIANA analyzers
Manufactured by	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Skin corrosion / irritation – Category 2 Serious eye damage / eye irritation – Category 1 Hazardous to the aquatic environment, acute hazard – Category 2
Signal word	Danger
Pictogram	
Hazard statements	H315 Causes skin irritation H318 Causes serious eye damage H401 Toxic to aquatic life
Precautionary statements	P264 Wash exposed skin thoroughly after handling. P273 Avoid release into the environment. P280 Wear protective gloves, protective clothing, eye protection, face protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P332 + P313 If skin irritation occurs: Get medical advice / attention P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor / physician P362 + P364 Take off contaminated clothing and wash it before reuse. P501 Dispose of contents/container in accordance with local, regional, and national regulations
Any hazards not otherwise classified	None

Section 3 Composition and Information on Ingredients	
Chemical characterization	Wash contains sodium hypochlorite
Chemical name	Sodium hypochlorite
Synonyms	Bleach
CAS number	7681-52-9
Concentration	5 – 6%

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor / physician.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	Toxic gases
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 30°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not available
ACGIH	Not available
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Emergency eye wash should be in the vicinity of use.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Clear light yellow to green liquid
Odor	Strong chlorine odor
Odor threshold	0.3 ppm
pH	~11 .0
Melting point / Freezing point	Not available
Initial boiling point and boiling range	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability (solid, gas)	Not available
Upper/lower flammability or explosive limits	Not available
Vapor pressure	12 mm Hg
Vapor density	Not available
Relative density	Not available
Solubility	Soluble in water
Partition coefficient	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	None identified
Hazardous reactions	Reacts violently with acids. May react violently with reducing agents. Contact with acids liberates toxic gas.
Hazardous polymerization	Will not polymerize
Incompatibilities	Strong acids, strong reducing agents, metals, ammonia
Hazard decomposition products	Hydrogen chloride, chlorine, phosgene
Conditions to avoid	Incompatible materials Direct sunlight; high and low temperatures

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	Not determined
Ingestion	May be harmful if swallowed
Skin contact	Causes skin irritation
Eye contact	Causes serious eye damage
Toxicity (LD50/LC50)	Dermal LD50: Rabbit: > 10 g/kg Oral LD50: Rat: 3-5 g/kg
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Acute hazard to aquatic enviroment
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container
Disposal methods	Dispose of this product as hazardous waste in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Dispose as hazardous waste. Avoid release into the environment
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Dispose as hazardous waste

Section 14 Transport Information	
UN Number	UN 1791
UN proper shipping name	Hypochlorite solutions
Transport hazard class	8
Packing group	III
Environmental hazards	Avoid release into the environment
Guidance on transport in bulk	Not determined
Special precautions on transport	Not determined

Section 15 Regulatory Information	
OSHA	This product meets the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Listed
SARA	
302	Not listed
311/312	Yes
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Listed on DSL
WHMIS Class	E
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	3	Health	3
Flammability	0	Flammability	0
Reactivity	1	Reactivity	1
Physical Hazards		Protective Equipment	H
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
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Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® Personal Use Kit

Section 1 Identification	
Product name	OC-Auto® Personal Use Kit
Catalog number	OCPU, OCPU with custom suffix
Recommended use	Collection and storage of patient samples for use in OC-Auto testing
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	Not applicable

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains no hazardous ingredients
Chemical name	HEPES
Synonyms	4-(2-Hydroxyethyl)piperazine-1-ethanesulfonic acid
CAS number	7365-45-9
Concentration	50 mM

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 30°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Clear colorless liquid
Odor	Odorless
Odor threshold	Not determined
pH	6.2 – 6.6
Melting point / Freezing point	Approximately 0°C
Initial boiling point and boiling range	Approximately 100°C
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Not applicable
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Not applicable

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards		Protective Equipment	B
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
The information in this SDS is believed to be accurate and complete at the time of revision. No warranty, express or implied, is made, and Polymedco assumes no legal responsibility or liability from its use. The user of our products is responsible for observing any applicable laws and guidelines.			

Polymedco Cancer Diagnostic Products, LLC. Safety Data Sheet

OC-Auto® Sampling Bottles

Section 1 Identification	
Product name	OC-Auto® Sampling Bottles
Catalog number	OCS1, OCS2, OCS3-KP, V-PZ25, V-PZ30
Recommended use	Collection and storage of patient samples for use in OC-Auto testing
Manufactured for	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	Not applicable

Section 3 Composition and Information on Ingredients	
Chemical characterization	Contains no hazardous ingredients
Chemical name	HEPES
Synonyms	4-(2-Hydroxyethyl)piperazine-1-ethanesulfonic acid
CAS number	7365-45-9
Concentration	50 mM

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 30°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Clear colorless liquid
Odor	Odorless
Odor threshold	Not determined
pH	6.2 – 6.6
Melting point / Freezing point	Approximately 0°C
Initial boiling point and boiling range	Approximately 100°C
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	Not determined
Hazardous reactions	Not determined
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	Not determined

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	None identified
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Not applicable
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Not applicable

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards		Protective Equipment	B
Date of preparation	22 September 2014		
Last revision date	26 February 2015		
The information in this SDS is believed to be accurate and complete at the time of revision. No warranty, express or implied, is made, and Polymedco assumes no legal responsibility or liability from its use. The user of our products is responsible for observing any applicable laws and guidelines.			

SAFETY DATA SHEET

Issuing date 02-Aug-2013 **Revision Date** 02-Aug-2013 **Version** 1

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product code 900612
Product name Para-Pak® C & S - CS9006

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Collection, transportation, preservation of stool specimens

1.3 Details of the supplier of the safety data sheet

Manufacturer
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

For further information, please contact:

E-mail Address www.meridianbioscience.com

1.4 Emergency telephone number

Emergency telephone Emergency telephone CHEMTREC (International) 1-800-424-9300/ For US 1-703-527-3887

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Classification according to EU Directives 67/548/EEC or 1999/45/EC
For the full text of the R-phrases mentioned in this Section, see Section 16

Symbol(s)
Not dangerous

2.2 Label elements

2.3 Other information

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

3.2 Mixtures

Chemical Name	EC-No	CAS-No	Weight %	Classification (67/548)	Classification (Reg. 1272/2008)	REACH Registration Number
Sodium chloride	Present	7647-14-5	0.495	-	no data available	no data available
Sodium thioglycolate	-	367-51-1	0.149	-	no data available	no data available
Agar	-	9002-18-0	0.149	-	no data available	no data available
Sodium phosphate dibasic	-	7558-79-4	0.109	-	no data available	no data available
Calcium chloride	233-140-8	10043-52-4	0.009	Xi; R36	Eye Irrit. 2 (H319)	no data available

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye contact Rinse thoroughly with plenty of water, also under the eyelids. If irritation persists, call a physician.

Skin contact Wash off immediately with soap and plenty of water.

Ingestion Rinse mouth. Clean mouth with water and drink afterwards plenty of water. Consult a physician if necessary.

Inhalation Move to fresh air. If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media
Dry chemical, CO_2, alcohol-resistant foam or water spray.

Extinguishing media which shall not be used for safety reasons
No information available.

5.2 Special hazards arising from the substance or mixture

None.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

See Section 12 for additional Ecological Information.

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up
Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

6.4 Reference to other sections

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling
Ensure adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions
Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3 Specific end uses

Other Guidelines
No information available.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Derived No Effect Level (DNEL)	No information available
Predicted No Effect Concentration (PNEC)	No information available

8.2 Exposure controls

Engineering Measures	Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Eye Protection	Tightly fitting safety goggles.
Hand Protection	Protective gloves.
Skin and body protection	Lightweight protective clothing.
Respiratory protection	No special protective equipment required.

Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental Exposure Controls	No information available.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	liquid		
Appearance	No information available	**Odor**	No information available
Color	red	**Odor Threshold**	No information available

Property	**Values**	**Remarks • Methods**
pH		No information available
Melting/freezing point		No information available
Boiling point/boiling range		No information available
Flash Point		No information available
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Flammability Limits in Air		No information available
upper flammability limit		
lower flammability limit		
Vapor pressure		No information available
Vapor density		No information available
Specific Gravity		No information available
Water solubility		No information available
Solubility in other solvents VALUE		No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Viscosity, kinematic		No information available
Viscosity, dynamic		
Explosive properties	No information available	
Oxidizing Properties	No information available	

9.2 Other information

Softening point	No information available
Molecular Weight	No information available
VOC Content(%)	No information available
Density VALUE	No information available
Bulk Density VALUE	No information available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

10.4 Conditions to Avoid

Extremes of temperature and direct sunlight.

10.5 Incompatible Materials

No materials to be especially mentioned.

10.6 Hazardous Decomposition Products

None under normal use conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Product Information Product does not present an acute toxicity hazard based on known or supplied information.

Inhalation There is no data available for this product.

Eye contact There is no data available for this product.

Skin contact There is no data available for this product.

Ingestion There is no data available for this product.

Acute toxicity 99.496% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	99,999.00 mg/kg
Dermal	99,999.00 mg/kg
Inhalation	
Gas	99,999.00 mg/l
Mist	99,999.00 mg/l
Vapor	99,999.00 mg/l

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium chloride	3 g/kg (Rat)	10 g/kg (Rabbit)	42 g/m³ (Rat) 1 h
Calcium chloride	1000 mg/kg (Rat)	2630 mg/kg (Rat)	

Skin corrosion/irritation No information available.

Eye damage/irritation No information available.

Sensitization No information available.

Germ Cell Mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

Specific target organ systemic toxicity (single exposure) No information available.

Specific target organ systemic toxicity (repeated exposure) No information available.

Aspiration hazard No information available.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants
.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates

Sodium chloride		5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Calcium chloride		10650: 96 h Lepomis macrochirus mg/L LC50 static	52: 48 h Daphnia magna mg/L EC50

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

Mobility
No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

IATA/DOT Not regulated

14.1.
14.2.
14.3.
14.4.
14.5.
14.6.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Chemical Name	French RG number

Sodium chloride	RG 78

International Inventories

TSCA	Complies
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

Legend
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2 Chemical Safety Report

No information available

SECTION 16. OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3
No information available

Issuing date	02-Aug-2013
Revision Date	02-Aug-2013
Revision Note	not applicable.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Disclaimer
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

SAFETY DATA SHEET

Data dell'edizione 02-ago-2013 **Data di revisione** 02-ago-2013 **Versione** 1

1. Identificazione della sostanza o della miscela e della società/impresa

1.1 Identificatore del prodotto

Codice prodotto 900612
Nome del prodotto Para-Pak® C & S - CS9006

1.2 Usi pertinenti identificati della sostanza o miscela e usi sconsigliati

Utilizzi raccomandati Collection, transportation, preservation of stool specimens

1.3 Informazioni sul fornitore della scheda di dati di sicurezza

Fabbricante
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Per ulteriori informazioni, contattare:

Indirizzo e-mail www.meridianbioscience.com

1.4 Numero telefonico di chiamata urgente

Numero telefonico di chiamata urgente Telefono di emergenza CHEMTREC (Internazionale) 1-800-424-9300 / Per gli Stati Uniti 1-703-527-3887

2. Identificazione dei pericoli

2.1 Classificazione della sostanza o della miscela

REGOLAMENTO (CE) N. 1272/2008

Classificazione secondo le Direttive EU 67/548/CEE o 1999/45/CE
Per il testo completo delle frasi R menzionate in questa sezione, riferirsi alla sezione 16

Simbolo(i)
Non pericoloso

2.2 Informazioni da indicare sull'etichetta

2.3 Altre informazioni

3. Composizione/informazione sugli ingredienti

3.1 Sostanze

3.2 Miscele

Nome Chimico	N. CE	N. CAS	Percentuale in peso	Classificazione (67/548)	Classificazione (Reg. 1272/2008)	Numero di registrazione REACH
Sodium chloride	Present	7647-14-5	0.495	-	nessun dato disponibile	nessun dato disponibile
Sodium thioglycolate	-	367-51-1	0.149	-	nessun dato disponibile	nessun dato disponibile
Agar	-	9002-18-0	0.149	-	nessun dato disponibile	nessun dato disponibile
Sodium phosphate dibasic	-	7558-79-4	0.109	-	nessun dato disponibile	nessun dato disponibile
Calcium chloride	233-140-8	10043-52-4	0.009	Xi; R36	Eye Irrit. 2 (H319)	nessun dato disponibile

Per il testo completo delle frasi R menzionate in questa sezione, riferirsi alla sezione 16

Per quanto riguarda il testo completo delle dichiarazioni-H menzionate in questo paragrafo, consultare il paragrafo 16

4. Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Contatto con gli occhi Sciacquare abbondantemente con molta acqua, anche sotto le palpebre. Se l'irritazione persiste, contattare un medico.

Contatto con la pelle Lavare subito con sapone ed acqua abbondante.

Ingestione Sciacquarsi la bocca. Sciacquare la bocca con acqua e berne abbondantemente. Se necessario consultare un medico.

Inalazione Portare all'aria aperta. In caso di persistenza dei disturbi consultare un medico.

4.2 Principali sintomi ed effetti, sia acuti e che ritardati

4.3 Indicazione per una consultazione medica immediata e per un adeguato trattamento medico speciale

Note per il medico Trattare sintomaticamente.

5. Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione appropriati
Composto chimico secco, CO2, schiuma resistente all’alcol o spruzzi d’acqua.

Mezzi di estinzione da non utilizzare per ragioni di sicurezza
Nessuna informazione disponibile.

5.2 Pericoli speciali derivanti dalla sostanza o dalla miscela

Nessuno(a).

5.3 Raccomandazioni per gli addetti all'estinzione degli incendi

In caso di incendio, indossare un apparato di respirazione autonomo e un dispositivo di protezione completo.

6. Misure in caso di fuoriuscita accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure in caso di emergenza

Prevedere una ventilazione adeguata.

Per ulteriori informazioni ecologiche, fare riferimento alla Sezione 12.

6.2 Precauzioni ambientali

Non sono richieste particolari misure precauzionali per la salvaguardia dell'ambiente.

6.3 Metodi e materiali per il contenimento e per la bonifica

Metodi di pulizia
Assorbire con terra, sabbia o altro materiale non combustibile e trasferire in contenitori per il successivo smaltimento.

6.4 Riferimenti ad altre sezioni

7. Manipolazione e immagazzinamento

7.1 Precauzioni per la manipolazione sicura

Avvertenze per un impiego sicuro
Prevedere una ventilazione adeguata.

7.2 Condizioni per lo stoccaggio sicuro, comprese eventuali incompatibilità

Misure tecniche/Modalità d'immagazzinaggio
Tenere i contenitori ben chiusi in un luogo secco, fresco e ben ventilato.

7.3 Usi finali particolari

Altre guide di riferimento
Nessuna informazione disponibile.

8. Controllo dell'esposizione/protezione individuale

8.1 Parametri di controllo

Limiti di esposizione	Questo prodotto, come viene fornito, non contiene alcuna sostanza pericolosa in base ai limiti di esposizione sul luogo di lavoro stabiliti dagli enti normativi specifici del paese
Livello derivato senza effetto (DNEL)	Nessuna informazione disponibile
La concentrazione prevedibile senza effetto (PNEC)	Nessuna informazione disponibile

8.2 Controlli dell'esposizione

Dati di progetto	Assicurare un'adeguata areazione, specialmente in zone chiuse.

Protezione individuale

Protezione degli occhi	Occhiali di sicurezza ben aderenti.
Protezione delle mani	Guanti di protezione.
Protezione della pelle e del corpo	vestito di protezione leggero.
Protezione respiratoria	Non e' richiesto un allestimento speciale di protezione.
Misure di igiene	Manipolare rispettando le buone pratiche di igiene industriale e di sicurezza adeguate.

Controlli dell'esposizione ambientale	Nessuna informazione disponibile.

9. Proprietà fisiche e chimiche

9.1 Informazioni sulle proprietà fisiche e chimiche fondamentali

Stato fisico	Liquido		
Aspetto	Nessuna informazione disponibile	**Odore**	Nessuna informazione disponibile
Colore	rosso	**Soglia di odore**	Nessuna informazione disponibile

Proprietà	**Valori**	**Osservazioni • Methods**
pH		Nessuna informazione disponibile
Punto di fusione/congelamento		Nessuna informazione disponibile
Punto/intervallo di ebollizione		Nessuna informazione disponibile
Punto di infiammabilità		Nessuna informazione disponibile
Tasso di evaporazione		Nessuna informazione disponibile
Infiammabilità (solidi, gas)		Nessuna informazione disponibile
Limiti d' infiammabilità nell'aria		Nessuna informazione disponibile
Limite superiore di infiammabilità		
limite inferiore di infiammabilità		
Pressione di vapore		Nessuna informazione disponibile
Densità di vapore		Nessuna informazione disponibile
Densità relativa		Nessuna informazione disponibile
Idrosolubilità		Nessuna informazione disponibile
Solubilità in altri solventi		Nessuna informazione disponibile
Coefficiente di ripartizione: n-ottanolo/acqua		Nessuna informazione disponibile
Temperatura di autoaccensione		Nessuna informazione disponibile
Temperatura di decomposizione		Nessuna informazione disponibile
Viscosità, cinematica		Nessuna informazione disponibile
Viscosità, dinamica		
Proprietà esplosive	Nessuna informazione disponibile	
Proprietà ossidanti	Nessuna informazione disponibile	

9.2 Altre informazioni

Punto di rammollimento	Nessuna informazione disponibile
Peso Molecolare	Nessuna informazione disponibile
Tenore di VOC (composti organici volatili)	Nessuna informazione disponibile
Densità	Nessuna informazione disponibile
Densità Apparente	Nessuna informazione disponibile

10. Stabilità e reattività

10.1 Reattività

10.2 Stabilità chimica

Stabile in condizioni normali.

10.3 Possibilità di reazioni pericolose

10.4 Condizioni da evitare

Temperature estreme e luce diretta del sole.

10.5 Materiali incompatibili

Non vi sono materiali che debbano essere specificatamente menzionati.

10.6 Prodotti di decomposizione pericolosi

Nessuno in condizioni normali d'uso.

11. INFORMAZIONI TOSSICOLOGICHE

11.1 Informazioni sugli effetti tossicologici

Tossicità acuta

Informazioni sul prodotto Il prodotto non presenta alcun pericolo di tossicità acuta, in base alle informazioni fornite o note.

Inalazione Non vi sono dati disponibili per questo prodotto.

Contatto con gli occhi Non vi sono dati disponibili per questo prodotto.

Contatto con la pelle Non vi sono dati disponibili per questo prodotto.

Ingestione Non vi sono dati disponibili per questo prodotto.

Tossicità acuta 99.496% della miscela consiste di un ingrediente (i) di tossicità sconosciuta.

The following values are calculated based on chapter 3.1 of the GHS document:

Orale	99,999.00 mg/kg
Dermico	99,999.00 mg/kg
Inalazione	
gas	99,999.00 mg/l
Nebbia	99,999.00 mg/l
Vapori	99,999.00 mg/l

Nome Chimico	LD50 Orale	LD50 Dermico	CL50 Inalazione
Sodium chloride	3 g/kg (Rat)	10 g/kg (Rabbit)	42 g/m³ (Rat) 1 h
Calcium chloride	1000 mg/kg (Rat)	2630 mg/kg (Rat)	

Corrosione/irritazione cutanea Nessuna informazione disponibile.

Danno agli occhi/irritazione Nessuna informazione disponibile.

Sensibilizzazione Nessuna informazione disponibile.

Mutagenicità sulle cellule germinali Nessuna informazione disponibile.

Cancerogenicità Nessuna informazione disponibile.

Tossicità per la riproduzione Nessuna informazione disponibile.

Tossicità specifica per organi bersaglio - esposizione singola Nessuna informazione disponibile.

Tossicità specifica per organi bersaglio - esposizione ripetuta Nessuna informazione disponibile.

Pericolo in caso di aspirazione Nessuna informazione disponibile.

12. Informazioni ecologiche

12.1 Tossicità

Effetti legati all'ecotossicità Non contiene sostanze riconosciute come pericolose per l'ambiente o non degradabili in impianti di trattamento di acqua di scolo.

Nome Chimico	Tossicità per le alghe	Tossicità per i pesci	Tossicità per la daphnia e per altri invertebrati acquatici
Sodium chloride		5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Calcium chloride		10650: 96 h Lepomis macrochirus mg/L LC50 static	52: 48 h Daphnia magna mg/L EC50

12.2 Persistenza e degradabilità

Nessuna informazione disponibile.

12.3 Potenziale di bioaccumulazione

Nessuna informazione disponibile.

12.4 Mobilità nel suolo

Mobilità
Nessuna informazione disponibile.

12.5 Risultati della valutazione PBT e vpvb

Nessuna informazione disponibile.

12.6 Altri effetti nocivi.

13. Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti dagli scarti / prodotti inutilizzati Eliminare nel rispetto della normativa vigente in materia.

Contenitori contaminati I contenitori vuoti dovrebbero essere trasportati in un sito autorizzato per il riciclaggio o l'eliminazione.

14. Informazioni sul trasporto

ICAO/IATA non regolamentato

14.1.
14.2.
14.3.
14.4.
14.5.
14.6.

15. Informazioni sulla regolamentazione

15.1 Norme e legislazione su salute, sicurezza e ambiente specifiche per la sostanza o la miscela

Nome Chimico	French RG number
Sodium chloride	RG 78

Inventari internazionali

TSCA	Attenente a
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
Cina	-
AICS	-
KECL	-

Legenda
TSCA – Inventario del Toxic Substances Control Act degli Stati Uniti, sezione 8(b)
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances (Inventario europeo delle sostanze chimiche esistenti a carattere commerciale /Lista europea delle sostanze chimiche notificate)
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List (Lista delle sostanze nazionali del Canada/ Lista delle sostanze non nazionali)
PICCS - Philippines Inventory of Chemicals and Chemical Substances (Inventario delle sostanze chimiche delle Filippine)
ENCS - Japan Existing and New Chemical Substances (Sostanze chimiche nuove ed esistenti in Giappone)
IECSC - China Inventory of Existing Chemical Substances (Inventario cinese delle sostanze chimiche esistenti)
AICS - Inventario Australiano di Sostanze Chimiche
\b KECL - Korean Existing and Evaluated Chemical Substances (Sostanze chimiche esistenti e valutate in Corea)

15.2 Valutazione della sicurezza chimica

Nessuna informazione disponibile

16. Altre informazioni

Testo integrale delle frasi R citate nei Capitoli 2 e 3
Nessuna informazione disponibile

Data dell'edizione 02-ago-2013

Data di revisione 02-ago-2013

Nota di Revisione non applicabile.

Questa scheda di sicurezza rispetta le prescrizioni del Regolamento (CE) Num. 1907/2006

Diniego
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Fine della Scheda Sicurezza Prodotto

FICHE DE DONNÉES DE SÉCURITÉ.

Date d'émission 02-août-2013 **Date de révision** 02-août-2013 **Version** 1

SECTION 1. Identification de la substance/du mélange et de la société/l'entreprise

1.1 Identificateur de produit

Code du produit 900612
Nom du produit Para-Pak® C & S - CS9006

1.2 Utilisations identifiées pertinentes de la substance ou du mélange et utilisations déconseillées

Utilisation recommandée Collection, transportation, preservation of stool specimens

1.3 Renseignements concernant le fournisseur de la fiche de données de sécurité

Fabricant
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Pour plus d'informations, veuillez prendre contact avec:

Adresse e-mail www.meridianbioscience.com

1.4 Numéro d'appel d'urgence

Numéro de téléphone d'appel d'urgence: Téléphone d'urgence CHEMTREC (International) 1-800-424-9300 / 1-703-527-3887 Pour américain

SECTION 2. Identification des dangers

2.1 Classification de la substance ou du mélange

RÈGLEMENT (CE) No 1272/2008

Classification conformément aux Directives UE 67/548/CEE ou 1999/45/CE
Pour le texte complet des Phrases-R mentionnées dans ce chapitre, voir section 16

Symbole(s)
Non dangereuse

2.2 Éléments d'étiquetage

2.3 Autres informations

SECTION 3. Composition/informations sur les composants

3.1 Substances

3.2 Mélanges

Nom Chimique	No.-CE	No.-CAS	Pour cent en poids	Classification (67/548)	Classification (Règ. 1272/2008)	Numéro d'Enregistrement REACH
Sodium chloride	Present	7647-14-5	0.495	-	donnée non disponible	donnée non disponible
Sodium thioglycolate	-	367-51-1	0.149	-	donnée non disponible	donnée non disponible
Agar	-	9002-18-0	0.149	-	donnée non disponible	donnée non disponible
Sodium phosphate dibasic	-	7558-79-4	0.109	-	donnée non disponible	donnée non disponible
Calcium chloride	233-140-8	10043-52-4	0.009	Xi; R36	Eye Irrit. 2 (H319)	donnée non disponible

Pour le texte complet des Phrases-R mentionnées dans ce chapitre, voir section 16

Pour le texte complet des Phrases-H mentionnées dans ce chapitre, voir section 16

SECTION 4. Premiers secours

4.1 Description des premiers secours

Contact avec les yeux Bien rincer avec beaucoup d'eau, y compris sous les paupières. Si l'irritation persiste, obtenir une attention médicale.

Contact avec la peau Laver immédiatement et abondamment avec de l'eau et du savon.

Ingestion Rincer la bouche. Se rincer la bouche à l'eau puis boire beaucoup d'eau. Consulter un médecin si nécessaire.

Inhalation Amener la victime à l'air libre. Si les troubles se prolongent, consulter un médecin.

4.2 Principaux symptômes et effets, aigus et différés

4.3 Indications quant à une prise en charge médicale immédiate ou d'un traitement spécial

Avis aux médecins Traiter de façon symptomatique.

SECTION 5. Mesures de lutte contre l'incendie

5.1 Moyens d'extinction

Moyens d'extinction appropriés
Dry chemical, CO_2, alcohol-resistant foam or water spray.

Moyen d'extinction à ne pas utiliser pour des raisons de sécurité
Pas d'information disponible.

5.2 Dangers particuliers résultant de la substance ou du mélange

aucun(e).

5.3 Conseils aux pompiers

Comme lors de tout incendie, porter un équipement respiratoire autonome et un équipement complet de protection.

SECTION 6. Mesures à prendre en cas de dispersion accidentelle

6.1 Précautions individuelles, équipement de protection et procédures d'urgence

Assurer une ventilation adéquate.

Voir la Rubrique 12 pour des informations supplémentaires sur les effets écologiques.

6.2 Précautions pour la protection de l'environnement

Pas de précautions spéciales pour l'environnement requises.

6.3 Méthodes et matériel de confinement et de nettoyage

Méthodes de nettoyage
Absorber avec de la terre, du sable ou un autre matériau non combustible et transférer dans des récipients pour élimination ultérieure.

6.4 Référence à d'autres sections

SECTION 7. Manipulation et stockage

7.1 Précautions à prendre pour une manipulation sans danger

Conseils pour une manipulation sans danger
Assurer une ventilation adéquate.

7.2 Conditions d'un stockage sûr, y compris d'éventuelles incompatibilités

Mesures techniques/Conditions de stockage
Garder les récipients bien fermés dans un endroit sec, frais et bien ventilé.

7.3 Utilisation(s) finale(s) particulière(s)

Autres lignes directrices
Pas d'information disponible.

SECTION 8. Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

Limites d'exposition	Ce produit tel qu'expédié ne contient pas de substance dangereuse dont les limites d'exposition professionnelle auraient été établies par les organismes de régulation locaux
Dose dérivée sans effet (DNEL)	Pas d'information disponible
Concentration prévisible sans effet (PNEC)	Pas d'information disponible

8.2 Contrôles de l'exposition

Mesures d'ordre technique	Assurer une ventilation adéquate, surtout dans les endroits clos.

Équipement de protection individuelle

Protection des yeux	Lunettes de sécurité à protection intégrale.
Protection des mains	Gants de protection.
Protection de la peau et du corps	Vêtement léger de protection.
Protection respiratoire	Ne nécessite pas d'équipement de protection spécial.

Mesures d'hygiène	À manipuler conformément aux bonnes pratiques d'hygiène industrielle et aux consignes de sécurité.
Contrôles d'exposition liés à la protection de l'environnement	Pas d'information disponible.

SECTION 9. Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques essentielles

État physique	liquide		
Aspect	Pas d'information disponible	**Odeur**	Pas d'information disponible
Couleur	rouge	**Seuil olfactif**	Pas d'information disponible

Propriété	**Valeurs**	**Remarques • Methods**
pH		Pas d'information disponible
Point de fusion/point de congélation		Pas d'information disponible
Point/intervalle d'ébullition		Pas d'information disponible
Point d'éclair		Pas d'information disponible
Taux d'évaporation		Pas d'information disponible
Inflammabilité (solide, gaz)		Pas d'information disponible
Limites d'inflammabilité dans l'air		Pas d'information disponible
limite d'inflammabilité supérieure		
limite d'inflammabilité inférieure		
Pression de vapeur		Pas d'information disponible
Densité de vapeur		Pas d'information disponible
Densité		Pas d'information disponible
Hydrosolubilité		Pas d'information disponible
Solubilité ds solvant - VALEUR		Pas d'information disponible
Coefficient de partage: n-octanol/eau		Pas d'information disponible
Température d'auto-inflammabilité		Pas d'information disponible
Température de décomposition		Pas d'information disponible
Viscosité, cinématique		Pas d'information disponible
Viscosité, dynamique		
Propriétés explosives	Pas d'information disponible	
Propriétés comburantes	Pas d'information disponible	

9.2 Autres informations

Point de ramollissement	Pas d'information disponible
Poids moléculaire	Pas d'information disponible
Teneur (%) en COV (composés organiques volatils)	Pas d'information disponible
Masse volumique VALEUR	Pas d'information disponible
Masse volumique apparente VALEUR	Pas d'information disponible

SECTION 10. Stabilité et réactivité

10.1 Réactivité

10.2 Stabilité chimique

Stable dans des conditions normales.

10.3 Possibilité de réactions dangereuses

10.4 Conditions à éviter

Températures extrêmes et lumière du soleil directe.

10.5 Matières incompatibles

Pas de matières à signaler spécialement.

10.6 Produits de décomposition dangereux

Aucun(e)(s) dans les conditions normales d'utilisation.

11. Informations toxicologiques

11.1 Informations sur les effets toxicologiques

Toxicité aiguë

Informations sur le produit Le produit ne présente pas de danger de toxicité aiguë d'après les informations connues ou divulguées le concernant.

Inhalation Il n'y a pas d'informations disponibles pour ce produit.

Contact avec les yeux Il n'y a pas d'informations disponibles pour ce produit.

Contact avec la peau Il n'y a pas d'informations disponibles pour ce produit.

Ingestion Il n'y a pas d'informations disponibles pour ce produit.

Toxicité aiguë 99.496% du mélange consiste en composant(s) dont la toxicité n'est pas connue.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral(e)	99,999.00 mg/kg
Dermale	99,999.00 mg/kg
Inhalation	
gaz	99,999.00 mg/l
Brouillard	99,999.00 mg/l
vapeur	99,999.00 mg/l

Nom Chimique	DL50 oral	DL50 dermal	CL50 par inhalation
Sodium chloride	3 g/kg (Rat)	10 g/kg (Rabbit)	42 g/m³ (Rat) 1 h
Calcium chloride	1000 mg/kg (Rat)	2630 mg/kg (Rat)	

Corrosion cutanée/irritation cutanée Pas d'information disponible.

Dommage/irritation de l'œil Pas d'information disponible.

Sensibilisation Pas d'information disponible.

Mutagénicité sur les cellules germinales Pas d'information disponible.

Cancérogénicité Pas d'information disponible.

Toxicité pour la reproduction Pas d'information disponible.

Toxicité spécifique pour certains organes cibles - exposition unique Pas d'information disponible.

Toxicité spécifique pour certains organes cibles - exposition répétée Pas d'information disponible.

Danger par aspiration Pas d'information disponible.

SECTION 12. Informations écologiques

12.1 Toxicité

Effets écotoxicologiques Ne contient pas de substances connues pour être dangereuses pour l'environnement ou non-dégradables dans des stations de traitement d'eaux usées.

Nom Chimique	Toxicité pour les algues	Toxicité pour le poisson	Toxicité pour la daphnie et les autres invertébrés aquatiques
Sodium chloride		5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Calcium chloride		10650: 96 h Lepomis macrochirus mg/L LC50 static	52: 48 h Daphnia magna mg/L EC50

12.2 Persistance et dégradabilité

Pas d'information disponible.

12.3 Potentiel de bioaccumulation

Pas d'information disponible.

12.4 Mobilité dans le sol

Mobilité
Pas d'information disponible.

12.5 Résultats des évaluations PBT et VPVB

Pas d'information disponible.

12.6 Autres effets néfastes.

SECTION 13. Considérations relatives à l'élimination

13.1 Méthodes de traitement des déchets

Déchets de résidus / produits non utilisés Eliminer le produit conformément à la réglementation locale en vigueur.

Emballages contaminés Les conteneurs vides doivent être acheminés vers un site agréé pour le traitement des déchets à des fins de recyclage ou d'élimination.

SECTION 14. Informations relatives au transport

ICAO/IATA non réglementé
14.1.

14.2.
14.3.
14.4.
14.5.
14.6.

SECTION 15. Informations réglementaires

15.1 Réglementations/législation particulières à la substance ou au mélange en matière de sécurité, de santé et d'environnement

Nom Chimique	tableaux du régime général
Sodium chloride	RG 78

Inventaires internationales

TSCA	Est conforme à (aux)
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
Chine	-
AICS	-
KECL	-

Légende
TSCA - Loi américaine sur le contrôle des substances toxiques, inventaire, rubrique 8(b)
EINECS/ELINCS – Inventaire européen des substances chimiques commerciales existantes/Liste européenne des substances chimiques notifiées
DSL/NDSL - Liste canadienne des substances domestiques/Liste canadienne des substances non domestiques
PICCS - Inventaire philippin des substances et produits chimiques
ENCS - Liste japonaise des substances chimiques existantes et nouvelles
IECSC - Inventaire chinois des substances chimiques existantes
AICS - Inventaire australien des substances chimiques
KECL - Liste coréenne des substances chimiques existantes et évaluées

15.2 Évaluation de la sécurité chimique

Pas d'information disponible

SECTION 16. Autres informations

Texte intégral des phrases R mentionnées sous les Chapitres 2 et 3
Pas d'information disponible

Date d'émission 02-août-2013

Date de révision 02-août-2013

Révision non applicable.

Cette fiche de données de sécurité est conforme aux exigences du Règlement (CE) No. 1907/2006

Clause de non-responsabilité
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Fin de la Fiche de Données de Sécurité

SAFETY DATA SHEET

Fecha de emisión 02-ago-2013 **Fecha de revisión** 02-ago-2013 **Versión** 1

1. Identificación de la sustancia o la mezcla y de la sociedad o la empresa

1.1 Identificador del producto

Código del producto 900612
Nombre del producto Para-Pak® C & S - CS9006

1.2 Usos pertinentes conocidos de la sustancia o de la mezcla y usos desaconsejados

Uso recomendado Collection, transportation, preservation of stool specimens

1.3 Datos del proveedor de la ficha de datos de seguridad

Fabricante
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Para informaciones complementarias, por favor ponerse en contacto con:

E-mail de contacto www.meridianbioscience.com

1.4 Teléfono de emergencia

Teléfono de urgencias Teléfono de urgencias CHEMTREC (International) 1-800-424-9300 / 1-703-527-3887 para EE.UU.

2. Identificación de los peligros

2.1 Clasificación de la sustancia o de la mezcla

REGLAMENTO (CE) No 1272/2008

Clasificación de acuerdo con las Directivas de la UE 67/548/CEE ó 1999/45/CE
El texto completo de las frases R mencionadas en esta Sección, se indica en la Sección 16

Símbolo(s)
No peligroso

2.2 Elementos de la etiqueta

2.3 Otra información

3. Composición/información sobre los componentes

3.1 Sustancias

3.2 Mezclas

Nombre químico	No. CE	No. CAS	Por ciento en peso	Clasificación (67/548)	Clasificación (Reg. 1272/2008)	Número de registro REACH
Sodium chloride	Present	7647-14-5	0.495	-	sin datos disponibles	sin datos disponibles
Sodium thioglycolate	-	367-51-1	0.149	-	sin datos disponibles	sin datos disponibles
Agar	-	9002-18-0	0.149	-	sin datos disponibles	sin datos disponibles
Sodium phosphate dibasic	-	7558-79-4	0.109	-	sin datos disponibles	sin datos disponibles
Calcium chloride	233-140-8	10043-52-4	0.009	Xi; R36	Eye Irrit. 2 (H319)	sin datos disponibles

El texto completo de las frases R mencionadas en esta Sección, se indica en la Sección 16

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16

4. Primeros auxilios

4.1 Descripción de los primeros auxilios

Contacto con los ojos Enjuagar cuidadosamente con abundante agua, también debajo de los párpados. Si la irritación persiste, llame a un médico.

Contacto con la piel Lávese inmediatamente con jabón y agua abundante.

Ingestión Enjuáguese la boca. Lavar la boca con agua y después beber agua abundante. Si es necesario consultar a un médico.

Inhalación Sacar al aire libre. Si los síntomas persisten consultar a un médico.

4.2 Principales síntomas y efectos, agudos y retardados

4.3 Indicación de la necesidad de recibir atención médica inmediata y de tratamiento especial

Notas para el médico Tratar sintomáticamente.

5. Medidas de lucha contra incendios

5.1 Medios de extinción

Medios de extinción apropiados
Dry chemical, CO_2, alcohol-resistant foam or water spray.

Medios de extinción que no deben utilizarse por razones de seguridad
No hay información disponible.

5.2 Peligros específicos derivados de la sustancia o la mezcla

Ninguno(a).

5.3 Recomendaciones para el personal de lucha contra incendios

Como en cualquier incendio, utilizar aparatos de respiración autónoma e indumentaria de protección completa.

6. Medidas en caso de vertido accidental

6.1 Precauciones personales, equipo de protección y procedimientos de emergencia

Asegúrese una ventilación apropiada.

Para más información ecológica, ver el apartado 12.

6.2 Precauciones relativas al medio ambiente

No se requieren precauciones especiales medioambientales.

6.3 Métodos y material de contención y de limpieza

Métodos de limpieza
Absorber con tierra, arena u otro material no combustible y transferir a contenedores para su posterior eliminación.

6.4 Referencia a otras secciones

7. Manipulación y almacenamiento

7.1 Precauciones para una manipulación segura

Consejos para una manipulación segura
Asegúrese una ventilación apropiada.

7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades

Medidas técnicas/Condiciones de almacenamiento
Cerrar los recipientes herméticamente y mantenerlos en lugar seco, fresco y bien ventilado.

7.3 Usos específicos finales

Otras directrices
No hay información disponible.

8. Controles de exposición/protección individual

8.1 Parámetros de control

Límites de exposición	Este producto, tal como se suministra, no contiene ningún material peligroso con límites de exposición ocupacional establecidos por los organismos reguladores regionales específicos
Nivel sin efecto derivado (DNEL)	No hay información disponible
Concentración prevista sin efecto (PNEC)	No hay información disponible

8.2 Controles de la exposición

Disposiciones de ingeniería	Asegurarse de una ventilación adecuada, especialmente en locales cerrados.

Protección personal

Protección de los ojos	Gafas de seguridad ajustadas al contorno del rostro.
Protección de las manos	Guantes protectores.
Protección de la piel y del cuerpo	ropa protectora ligera.
Protección respiratoria	No se requiere equipo especial de protección.
Medidas de higiene	Manipular con las precauciones de higiene industrial adecuadas, y respetar las prácticas de seguridad.
Controles de exposición medioambiental	No hay información disponible.

9. Propiedades físicas y químicas

9.1 Información sobre propiedades físicas y químicas básicas

Estado físico	líquido		
Aspecto	No hay información disponible	**Olor**	No hay información disponible
Color	rojo	**Umbral olfativo**	No hay información disponible

Propiedades	**Valores**	**Observaciones • Methods**
pH		No hay información disponible
Punto de fusión / punto de congelación		No hay información disponible
Punto /intervalo de ebullición		No hay información disponible
Punto de inflamación		No hay información disponible
Tasa de evaporación		No hay información disponible
Inflamabilidad (sólido, gas)		No hay información disponible
Límites de Inflamabilidad en el Aire		No hay información disponible
límite de inflamabilidad superior		
límite de inflamabilidad inferior		
Presión de vapor		No hay información disponible
Densidad de vapor		No hay información disponible
Gravedad Específicas		No hay información disponible
Solubilidad en agua		No hay información disponible
Solubilidad en otros disolventes		No hay información disponible
Coeficiente de reparto n-octanol/agua		No hay información disponible
Temperatura de auto-inflamación		No hay información disponible
Temperatura de descomposición		No hay información disponible
Viscosidad, cinemática		No hay información disponible
Viscosidad, dinámica		
Propiedades explosivas	No hay información disponible	
Propiedades comburentes	No hay información disponible	

9.2 Otra información

Temperatura de reblandecimiento	No hay información disponible
Peso molecular	No hay información disponible
Contenido (%) COV (compuestos orgánicos volátiles)	No hay información disponible
Densidad	No hay información disponible
Densidad aparente	No hay información disponible

10. Estabilidad y reactividad

10.1 Reactividad

10.2 Estabilidad química

Estable en condiciones normales.

10.3 Posibilidad de reacciones peligrosas

10.4 Condiciones que deben evitarse

Temperaturas extremas y luz directa del sol.

10.5 Materiales incompatibles

Ningún material a mencionar especialmente.

10.6 Productos de descomposición peligrosos

Ninguno en las condiciones de uso normales.

11. INFORMACIÓN TOXICOLÓGICA

11.1 Información sobre los efectos toxicológicostoxicidad aguda

Toxicidad aguda

Información del Producto El producto no presenta un riesgo agudo de toxicidad basado en la información conocida o proporcionada.

Inhalación No existe ningún dato disponible para ese producto.

Contacto con los ojos No existe ningún dato disponible para ese producto.

Contacto con la piel No existe ningún dato disponible para ese producto.

Ingestión No existe ningún dato disponible para ese producto.

Toxicidad aguda 99.496% la mezcla consiste de ingrediente(s) de toxicidad desconocida.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	99,999.00 mg/kg
Cutáneo	99,999.00 mg/kg
Inhalación	
gas	99,999.00 mg/l
Niebla	99,999.00 mg/l
Vapor	99,999.00 mg/l

Nombre químico	DL50 Oral	DL50 cutánea	CL50 Inhalación
Sodium chloride	3 g/kg (Rat)	10 g/kg (Rabbit)	42 g/m³ (Rat) 1 h
Calcium chloride	1000 mg/kg (Rat)	2630 mg/kg (Rat)	

Corrosión o irritación cutáneas No hay información disponible.

Daño a los ojos/irritación No hay información disponible.

Sensibilización No hay información disponible.

Mutagenicidad en células germinales No hay información disponible.

Carcinogenicidad No hay información disponible.

Toxicidad para la reproducción No hay información disponible.

Toxicidad específica en determinados órganos - exposición única No hay información disponible.

Toxicidad específica en determinados órganos - exposiciones repetidas No hay información disponible.

Peligro de aspiración No hay información disponible.

12. Información ecológica

12.1 Toxicidad

Efectos ecotoxicológicos No contiene sustancias nocivas para el entorno o no degradables en las estaciones de tratamiento de aguas residuales.

Nombre químico	Toxicidad para las algas	Toxicidad para los peces	Toxicidad para las dafnias y otros invertebrados acuáticos
Sodium chloride		5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Calcium chloride		10650: 96 h Lepomis macrochirus mg/L LC50 static	52: 48 h Daphnia magna mg/L EC50

12.2 Persistencia y degradabilidad

No hay información disponible.

12.3 Potencial de bioacumulación

No hay información disponible.

12.4 Movilidad en el suelo

Movilidad
No hay información disponible.

12.5 Resultados de la valoración PBT y MPMB

No hay información disponible.

12.6 Otros efectos adversos.

13. Consideraciones relativas a la eliminación

13.1 Métodos para el tratamiento de residuos

Desechos de residuos / producto no utilizado Eliminar, observando las normas locales en vigor.

Envases contaminados Los contenedores vacíos deben ser llevados a un sitio de manejo aprobado para desechos, para el reciclado o eliminación.

14. Información relativa al transporte

ICAO/IATA no regulado

14.1.
14.2.
14.3.
14.4.
14.5.

14.6.

15. Información reglamentaria

15.1 Reglamentación y legislación en materia de seguridad, salud y medio ambiente específicas para la sustancia o la mezcla

Nombre químico	French RG number
Sodium chloride	RG 78

Inventarios Internacionales

TSCA	Cumple
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
China	-
AICS	-
KECL	-

Leyenda
TSCA : Ley de Control de Sustancias Tóxicas estadounidense, apartado 8(b), Inventario
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL : Lista de Sustancias Domésticas Canadiense/Lista de Sustancias No Domésticas Canadiense
PICCS - Inventario filipino de sustancias y preparados químicos
ENCS - Inventario japonés de sustancias químicas existentes y nuevas
IECSC - Inventario chino de sustancias químicas existentes
AICS - Inventario australiano de sustancias químicas
KECL - Inventario coreano de sustancias químicas existentes y evaluadas

15.2 Evaluación de la seguridad química

No hay información disponible

16. Otra información

El texto completo de las frases-R referidas en los puntos 2 y 3
No hay información disponible

Fecha de emisión 02-ago-2013

Fecha de revisión 02-ago-2013

Nota de revisión no aplicable.

La hoja técnica de seguridad cumple con los requisitos de la Reglamento (CE) No. 1907/2006

De responsabilidad
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Fin de la Ficha de Datos de Seguridad

SAFETY DATA SHEET

Ausgabedatum 02-Aug-2013 **Überarbeitet am** 02-Aug-2013 **Version** 1

1. Bezeichnung des Stoffs bzw. des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktnummer 900612
Produktname Para-Pak® C & S - CS9006

1.2 Relevante ermittelte Verwendungszwecke des Stoffs oder Gemischs und Verwendungszwecke, von denen abgeraten wird

Empfohlener Anwendungsbereich Collection, transportation, preservation of stool specimens

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Für weitere Informationen bitte kontaktieren:

Email-Adresse www.meridianbioscience.com

1.4 Notfall-Telefonnummer

Notrufnummer Notrufnummer CHEMTREC (International) 1-800-424-9300 / für USA 1-703-527-3887

2. Mögliche Gefahren

2.1 Einstufung des Stoffs oder Gemischs

VERORDNUNG (EG) Nr. 1272/2008

Einstufung gemäss EU-Richtlinien 67/548/EWG oder 1999/45/EG
Den vollen Wortlaut der hier genannten R-Sätze finden Sie in Abschnitt 16

Symbol(e)
Nicht gefährlich

2.2 Kennzeichnungselemente

2.3 Sonstige Angaben

3. Zusammensetzung/Angaben zu Bestandteilen

3.1 Stoffe

3.2 Gemische

Chemische Bezeichnung	EG-Nr	CAS-Nr	Gewichtsprozent	Einstufung (67/548)	Einstufung (VO (EG) 1272/2008)	REACH Registrierungsnummer
Sodium chloride	Present	7647-14-5	0.495	-	Keine Daten verfügbar	Keine Daten verfügbar
Sodium thioglycolate	-	367-51-1	0.149	-	Keine Daten verfügbar	Keine Daten verfügbar
Agar	-	9002-18-0	0.149	-	Keine Daten verfügbar	Keine Daten verfügbar
Sodium phosphate dibasic	-	7558-79-4	0.109	-	Keine Daten verfügbar	Keine Daten verfügbar
Calcium chloride	233-140-8	10043-52-4	0.009	Xi; R36	Eye Irrit. 2 (H319)	Keine Daten verfügbar

Den vollen Wortlaut der hier genannten R-Sätze finden Sie in Abschnitt 16

Den Volltext der in diesem Abschnitt aufgeführten Gefahrenhinweise finden sie unter Abschnitt 16

4. Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Augenkontakt Sorgfältig mit viel Wasser ausspülen, auch unter den Augenlidern. Bei anhaltender Reizung ärztliche Hilfe hinzuziehen.

Hautkontakt Sofort mit Seife und viel Wasser abwaschen.

Verschlucken Mund ausspülen. Mund mit Wasser ausspülen und reichlich Wasser nachtrinken. Falls erforderlich einen Arzt konsultieren.

Einatmen An die frische Luft bringen. Bei anhaltenden Beschwerden einen Arzt aufsuchen.

4.2 Wichtigste sowohl akute als auch verzögerte Symptome und Auswirkungen

4.3 Angabe der benötigten ärztlichen Soforthilfe und Spezialbehandlung

Hinweise für den Arzt Symptomatische Behandlung.

5. Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel
Dry chemical, CO_2, alcohol-resistant foam or water spray.

Löschmittel, die aus Sicherheitsgründen nicht zu verwenden sind
Keine Information verfügbar.

5.2 Besondere von dem betreffenden Stoff oder Gemisch ausgehende Gefahren

kein(e,er).

5.3 Hinweise für die Brandbekämpfung

Wie bei jedem Feuer schweres Atemschutzgerät und volle Schutzausrüstung tragen.

6. Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Für angemessene Lüftung sorgen.

Weitere Angaben zur Ökologie im Abschnitt 12.

6.2 Umweltschutzmaßnahmen

Keine besonderen Umweltschutzmaßnahmen erforderlich.

6.3 Methoden und Material für Eindämmung und Reinigung

Reinigungsverfahren
Mit Erde, Sand oder anderen nicht brennbaren Materialien aufsaugen und zur späteren Entsorgung in Behälter füllen.

6.4 Verweis auf andere Abschnitte

7. Handhabung und Lagerung

7.1 Vorsichtsmaßnahmen für eine sichere Handhabung

Hinweise zum sicheren Umgang
Für angemessene Lüftung sorgen.

7.2 Bedingungen für eine sichere Lagerung unter Berücksichtigung von Unverträglichkeiten

Technische Maßnahmen/Lagerungsbedingungen
Behälter dicht geschlossen an einem trockenen, kühlen und gut gelüfteten Ort aufbewahren.

7.3 Spezifische Endverwendungszwecke

Andere Richtlinien
Keine Information verfügbar.

8. Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstungen

8.1 Zu überwachende Parameter

Expositionsgrenzwerte	Das Produkt enthält in der gelieferten Form keine Gefahrstoffe mit von den für die Region zuständigen Bestimmungsbehörden festgelegten Expositionsgrenzen am Arbeitsplatz
Abgeleitete Expositionshöhe ohne Beeinträchtigung (DNEL)	Keine Information verfügbar
Abgeschätzte Nicht-Effekt-Konzentration (PNEC)	Keine Information verfügbar

8.2 Begrenzung und Überwachung der Exposition

Technische Schutzmaßnahmen	Für ausreichende Belüftung sorgen, besonders in geschlossenen Räumen.

Persönliche Schutzausrüstung

Augenschutz	Dicht schließende Schutzbrille.
Handschutz	Schutzhandschuhe.
Haut- und Körperschutz	Leichter Schutzanzug.
Atemschutz	Keine besondere Schutzausrüstung erforderlich.

Hygienemaßnahmen	Die beim Umgang mit Chemikalien üblichen Vorsichtsmaßnahmen sind zu beachten.

Begrenzung und Überwachung der Umweltexposition Keine Information verfügbar.

9. Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Aggregatzustand	Flüssigkeit		
Aussehen	Keine Information verfügbar	**Geruch**	Keine Information verfügbar
Farbe	rot	**Geruchsschwelle**	Keine Information verfügbar

Eigenschaft	**Werte**	**Bemerkungen • Methods**
pH-Wert		Keine Information verfügbar
Schmelzpunkt/Gefrierpunkt		Keine Information verfügbar
Siedepunkt/Siedebereich		Keine Information verfügbar
Flammpunkt		Keine Information verfügbar
Verdampfungsgeschwindigkeit		Keine Information verfügbar
Entzündbarkeit (fest, gasförmig)		Keine Information verfügbar
Entzündlichkeitsgrenzwert in der Luft		Keine Information verfügbar
obere Zündgrenze		
untere Zündgrenze		
Dampfdruck		Keine Information verfügbar
Dampfdichte		Keine Information verfügbar
Spezifisches Gewicht		Keine Information verfügbar
Wasserlöslichkeit		Keine Information verfügbar
Löslichkeit in anderen Lösungsmitteln		Keine Information verfügbar
Verteilungskoeffizient: n-Octanol/Wasser		Keine Information verfügbar
Selbstentzündungstemperatur		Keine Information verfügbar
Zersetzungstemperatur		Keine Information verfügbar
Viskosität, kinematisch		Keine Information verfügbar
Viskosität, dynamisch		
Explosionsgefahr	Keine Information verfügbar	
Oxidierende Eigenschaften	Keine Information verfügbar	

9.2 Sonstige Angaben

Erweichungspunkt	Keine Information verfügbar
Molekulargewicht	Keine Information verfügbar
Gehalt (%)der flüchtigen organischen Verbindung	Keine Information verfügbar
Dichte	Keine Information verfügbar
Schüttdichte	Keine Information verfügbar

10. Stabilität und Reaktivität

10.1 Reaktivität

10.2 Chemische Stabilität

Stabil unter normalen Bedingungen.

10.3 Möglichkeit gefährlicher Reaktionen

10.4 Zu vermeidende Bedingungen

Extreme Temperaturen und direkte Sonneneinstrahlung.

10.5 Unverträgliche Materialien

Keine besonders zu erwähnenden Stoffe.

10.6 Gefährliche Zersetzungsprodukte

Bei normalen Verwendungsbedingungen keine.

11. Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

Akute Toxizität

Produktinformation Das Produkt stellt gemäß bekannter oder verfügbarer Informationen keine akute Vergiftungsgefahr dar.

Einatmen Für dieses Produkt sind keine Daten verfügbar.

Augenkontakt Für dieses Produkt sind keine Daten verfügbar.

Hautkontakt Für dieses Produkt sind keine Daten verfügbar.

Verschlucken Für dieses Produkt sind keine Daten verfügbar.

Akute Toxizität 99.496% der Mischung besteht aus einem Bestandteil/Bestandteilen mit unbekannter Toxizität.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	99,999.00 mg/kg
Haut	99,999.00 mg/kg
Einatmen	
Gas	99,999.00 mg/l
Nebel	99,999.00 mg/l
Dampf	99,999.00 mg/l

Chemische Bezeichnung	LD50 Oral	LD50 Dermal	LC50 Einatmen
Sodium chloride	3 g/kg (Rat)	10 g/kg (Rabbit)	42 g/m³ (Rat) 1 h
Calcium chloride	1000 mg/kg (Rat)	2630 mg/kg (Rat)	

Ätz-/Reizwirkung auf die Haut Keine Information verfügbar.

Augenschaden/-reizung Keine Information verfügbar.

Sensibilisierung Keine Information verfügbar.

Keimzell-Mutagenität Keine Information verfügbar.

Karzinogenität Keine Information verfügbar.

Reproduktionstoxizität Keine Information verfügbar.

Spezifische Zielorgan-Toxizität - einmalige Exposition Keine Information verfügbar.

Spezifische Zielorgan-Toxizität - wiederholte Exposition Keine Information verfügbar.

Aspirationsgefahr Keine Information verfügbar.

12. Umweltbezogene Angaben

12.1 Toxizität

Ökotoxische Wirkungen Enthält keine Stoffe, die bekanntermaßen umweltgefährlich sind oder die in Kläranlagen nicht abgebaut werden.

Chemische Bezeichnung	Toxizität gegenüber Algen	Toxizität gegenüber Fischen	Toxizität gegenüber Daphnien und anderen wirbellosen Wassertieren
Sodium chloride		5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Calcium chloride		10650: 96 h Lepomis macrochirus mg/L LC50 static	52: 48 h Daphnia magna mg/L EC50

12.2 Persistenz und Abbaubarkeit

Keine Information verfügbar.

12.3 Bioakkumulationspotenzial

Keine Information verfügbar.

12.4 Mobilität im Boden

Mobilität
Keine Information verfügbar.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Keine Information verfügbar.

12.6 Andere schädliche Wirkungen.

13. Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Abfälle von Restmengen / ungebrauchten Produkten Unter Beachtung der örtlichen behördlichen Bestimmungen beseitigen.

Verunreinigte Verpackungen Leere Behälter einer anerkannten Abfallentsorgungsanlage zuführen zwecks Wiedergewinnung oder Entsorgung.

14. Angaben zum Transport

ICAO/IATA nicht reguliert
14.1.
14.2.

14.3.
14.4.
14.5.
14.6.

15. Rechtsvorschriften

15.1 Vorschriften zu Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

Chemische Bezeichnung	French RG number
Sodium chloride	RG 78

Internationale Bestandsverzeichnisse

TSCA	Erfüllt
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
China	-
AICS	-
KECL	-

Legende
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory - Verzeichnis nach §8(b) des Gesetzes zur Minderung toxischer Stoffe (TSCA) der USA
EINECS/ELINCS - Europäisches Verzeichnis existierender kommerzieller chemischer Substanzen/Eu Liste der angemeldeten chemischen Stoffe
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List - Kanadisches Chemikalienverzeichis Inland/Ausland
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances - Japanisches Verzeichnis chemischer Alt- und Neustoffe
IECSC - China Inventory of Existing Chemical Substances
AICS – Australischer Warenbestand der chemischen Substanzen
KECL - Korean Existing and Evaluated Chemical Substances - Südkoreanisches Chemikalienverzeichnis

15.2 Stoffsicherheitsbeurteilung

Keine Information verfügbar

16. Sonstige Angaben

Vollständiger Wortlaut der in den Kapiteln 2 und 3 aufgeführten R-Sätze
Keine Information verfügbar

Ausgabedatum 02-Aug-2013

Überarbeitet am 02-Aug-2013

Abänderungsvermerk nicht anwendbar.

Dieses Sicherheitsdatenblatt erfüllt die Anforderungen der Verordnung (EG) Nr. 1907/2006

Haftungsausschluss
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Ende des Sicherheitsdatenblatts

VEILIGHEIDSINFORMATIEBLAD.

Datum van uitgifte 02-aug-2013 **Herzieningsdatum** 02-aug-2013 **Versie** 1

Identificatie van de stof of het mengsel en van de vennootschap/onderneming

1.1 Productidentificatie

Productcode 900612
Productbenaming Para-Pak® C & S - CS9006

1.2 Relevant geïdentificeerd gebruik van de stof of het mengsel en ontraden gebruik

Aanbevolen gebruik Collection, transportation, preservation of stool specimens

1.3 Details betreffende de verstrekker van het veiligheidsinformatieblad

Fabrikant
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Voor verdere informatie contact opnemen met:

E-mailadres www.meridianbioscience.com

1.4 Telefoonnummer voor noodgevallen

Telefoonnummer voor noodgevallen Telefoonnummer voor noodgevallen CHEMTREC (International) 1-800-424-9300 / Voor de Verenigde Staten 1-703-527-3887

2. Identificatie van de gevaren

2.1 Indeling van de stof of het mengsel

VERORDENING (EG) Nr. 1272/2008

Classificatie volgens EU-Richtlijnen 67/548/EEG of 1999/45/EG
Voor de volledige tekst van de R-zinnen die worden genoemd in deze paragraaf, zie Paragraaf 16

Symbo(o)l(en)
Niet gevaarlijk.

2.2 Etiketteringselementen

2.3 Overige informatie

3. Samenstelling en informatie over de bestanddelen

3.1 Stoffen

3.2 Mengsels

Chemische naam	EG-Nr	CAS-Nr	Massaprocent	Indeling (67/548)	GHS Classificatie	REACH registratienummer
Sodium chloride	Present	7647-14-5	0.495	-	geen gegevens beschikbaar	geen gegevens beschikbaar
Sodium thioglycolate	-	367-51-1	0.149	-	geen gegevens beschikbaar	geen gegevens beschikbaar
Agar	-	9002-18-0	0.149	-	geen gegevens beschikbaar	geen gegevens beschikbaar
Sodium phosphate dibasic	-	7558-79-4	0.109	-	geen gegevens beschikbaar	geen gegevens beschikbaar
Calcium chloride	233-140-8	10043-52-4	0.009	Xi; R36	Eye Irrit. 2 (H319)	geen gegevens beschikbaar

Voor de volledige tekst van de R-zinnen die worden genoemd in deze paragraaf, zie Paragraaf 16

Voor de volledige text van H-zinnen zoals vermeld in deze paragraaf, zie paragraaf 16

4. Eerstehulpmaatregelen

4.1 Beschrijving van de eerstehulpmaatregelen

Aanraking met de ogen Grondig spoelen met veel water, ook onder de oogleden. Raadpleeg een arts indien de irritatie aanhoudt.

Aanraking met de huid Onmiddellijk afwassen met zeep en veel water.

Inslikken Mond spoelen. Mond reinigen met water en daarna veel water drinken. Indien nodig een arts raadplegen.

Inademing In de frisse lucht brengen. Indien symptomen aanhouden, een arts raadplegen.

4.2 Belangrijkste acute en uitgestelde symptomen en effecten

4.3 Indicatie van onmiddelijke medische hulp en vereiste speciale behandeling

Opmerkingen voor de arts Symptomatisch behandelen.

5. Brandbestrijdingsmaatregelen

5.1 Blusmiddelen

Geschikte blusmiddelen
Droogpoeder, kooldioxide (CO2), alcoholbestendig schuim, of verneveld water.

Blusmiddelen die om veiligheidsredenen niet gebruikt mogen worden
Geen gegevens beschikbaar.

5.2 Speciale gevaren die door de stof of het mengsel worden veroorzaakt

Geen.

5.3 Advies voor brandweerlieden

Draag, net als bij elke andere brand, onafhankelijke ademhalingsapparatuur en een volledig beschermende uitrusting.

6. Maatregelen bij het accidenteel vrijkomen van de stof of het mengsel

6.1 Persoonlijke voorzorgsmaatregelen, beschermde uitrusting en noodprocedures

Zorg voor voldoende ventilatie.

Zie sectie 12 voor aanvullende ecologische informatie.

6.2 Milieuvoorzorgsmaatregelen

Geen speciale morsingsvoorzorgsmaatregelen voor het milieu vereist.

6.3 Insluitings- en reinigingsmethoden en -materiaal

Reinigingsmethoden
Absorberen met aarde, zand of een ander niet-ontvlambaar materiaal en overbrengen naar vaten voor latere verwijdering.

6.4 Verwijzing naar andere rubrieken

7. Hantering en opslag

7.1 Voorzorgsmaatregelen voor het veilig hanteren van de stof of het mengsel

Advies voor veilige hantering
Zorg voor voldoende ventilatie.

7.2 Voorwaarden voor een veilige opslag, met inbegrip van incompatibele producten

Technische maatregelen/Opslagomstandigheden
Containers goed gesloten bewaren op een droge, koele en goed geventileerde plaats.

7.3 Specifiek eindgebruik

Overige richtlijnen
Geen gegevens beschikbaar.

8. Maatregelen ter beheersing van blootstelling/persoonlijke bescherming

8.1 Controleparameters

Blootstellingslimieten	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Afgeleide doses zonder effect (DNEL)	Geen gegevens beschikbaar
Voorspelde concentraties zonder effect (PNEC)	Geen gegevens beschikbaar

8.2 Maatregelen ter beheersing van blootstelling

Technische maatregelen	Voor geschikte ventilatie zorgen, vooral in gesloten ruimten.
Persoonlijke beschermingsmiddelen	
Bescherming van de ogen	Nauw aansluitende veiligheidsstofbril.
Bescherming van de handen	Beschermende handschoenen.
Huid- en lichaamsbescherming	Lichtgewicht beschermende kleding.
Bescherming van de ademhalingswegen	Geen speciale beschermingsmiddelen nodig.
Hygiënische maatregelen	Gebruiken volgens goede industriële hygiëne en veiligheid.

Beheersing van milieublootstelling Geen gegevens beschikbaar.

9. Fysische en chemische eigenschappen

9.1 Informatie over fysische en chemische basiseigenschappen

Fysische toestand	vloeibaar		
Voorkomen	Geen gegevens beschikbaar	**Geur**	Geen gegevens beschikbaar
Kleur	rood	**Geurdrempelwaarde**	Geen gegevens beschikbaar

Eigenschap	**Waarden**	**Opmerkingen • Methods**
pH		Geen gegevens beschikbaar
Smelt-/vriespunt		Geen gegevens beschikbaar
Kookpunt/kooktraject		Geen gegevens beschikbaar
Vlampunt		Geen gegevens beschikbaar
Verdampingssnelheid		Geen gegevens beschikbaar
Ontvlambaarheid (vast, gas)		Geen gegevens beschikbaar
Ontvlambaarheidgrenzen in lucht		Geen gegevens beschikbaar
hoogste vlampunt		
laagste vlampunt		
Dampspanning		Geen gegevens beschikbaar
Dampdichtheid		Geen gegevens beschikbaar
Soortelijk gewicht		Geen gegevens beschikbaar
Oplosbaarheid in water		Geen gegevens beschikbaar
Oplosbaarheid in andere oplosmiddelen		Geen gegevens beschikbaar
Verdelingscoëfficiënt: n-octanol/water		Geen gegevens beschikbaar
Zelfontbrandingstemperatuur		Geen gegevens beschikbaar
Ontledingstemperatuur		Geen gegevens beschikbaar
Viscositeit, kinematisch		Geen gegevens beschikbaar
Viscositeit, dynamisch		
Ontploffingseigenschappen	Geen gegevens beschikbaar	
Oxiderende eigenschappen	Geen gegevens beschikbaar	

9.2 Overige informatie

Verwekingspunt	Geen gegevens beschikbaar
Moleculair gewicht	Geen gegevens beschikbaar
VOS (vluchtige organische stoffen) gehalte (%)	Geen gegevens beschikbaar
Dichtheid	Geen gegevens beschikbaar
Bulk soortelijk gewicht	Geen gegevens beschikbaar

10. Stabiliteit en reactiviteit

10.1 Reactiviteit

10.2 Chemische stabiliteit

Stabiel onder normale omstandigheden.

10.3 Mogelijke gevaarlijke reacties

10.4 Te vermijden omstandigheden

Extreme temperaturen en direct zonlicht.

10.5 Chemisch op elkaar inwerkende materialen

Geen materialen om speciaal te vermelden.

10.6 Gevaarlijke ontledingsproducten

Geen, bij normaal gebruik.

11. TOXICOLOGISCHE INFORMATIE

11.1 Informatie over toxicologische effecten

Acute toxiciteit

Productinformatie Het product levert op basis van bekende of geleverde informatie geen gevaar voor acute toxiciteit.

Inademing Over dit product zijn geen gegevens beschikbaar.

Aanraking met de ogen Over dit product zijn geen gegevens beschikbaar.

Aanraking met de huid Over dit product zijn geen gegevens beschikbaar.

Inslikken Over dit product zijn geen gegevens beschikbaar.

Acute toxiciteit 99.496% van het mengsel bestaat uit bestanddelen waarvan over de toxiciteit niets bekend is.

The following values are calculated based on chapter 3.1 of the GHS document:

Oraal	99,999.00 mg/kg
Huid	99,999.00 mg/kg
Inademing	
gas	99,999.00 mg/l
Nevels	99,999.00 mg/l
Damp	99,999.00 mg/l

Chemische naam	LD50 oraal	LD50 huid	LC50 Inademen
Sodium chloride	3 g/kg (Rat)	10 g/kg (Rabbit)	42 g/m³ (Rat) 1 h
Calcium chloride	1000 mg/kg (Rat)	2630 mg/kg (Rat)	

Huidcorrosie/-irritatie Geen gegevens beschikbaar.

Oogletsel/-irritatie Geen gegevens beschikbaar.

Sensibilisering Geen gegevens beschikbaar.

Mutageniciteit in geslachtscellen Geen gegevens beschikbaar.

Kankerverwekkendheid Geen gegevens beschikbaar.

Giftigheid voor de voortplanting Geen gegevens beschikbaar.

Specifieke doelorgaantoxiciteit - eenmalige blootstelling Geen gegevens beschikbaar.

Specifieke doelorgaantoxiciteit - herhaalde blootstelling Geen gegevens beschikbaar.

Aspiratiegevaar Geen gegevens beschikbaar.

12. Ecologische informatie

12.1 Toxiciteit

Ecotoxiciteitseffecten Bevat geen stoffen die bekend zijn als gevaarlijk voor het milieu of niet afbreekbaar in waterzuiveringsinstallaties.

Chemische naam	Toxiciteit voor algen	Toxiciteit voor vissen	Toxiciteit voor dafnia's en andere ongewervelde waterdieren
Sodium chloride		5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Calcium chloride		10650: 96 h Lepomis macrochirus mg/L LC50 static	52: 48 h Daphnia magna mg/L EC50

12.2 Persistentie en afbreekbaarheid

Geen gegevens beschikbaar.

12.3 Bioaccumulatie

Geen gegevens beschikbaar.

12.4 Mobiliteit in de bodem

Mobiliteit
Geen gegevens beschikbaar.

12.5 Resultaten van PBT- en zPzB-beoordeling

Geen gegevens beschikbaar.

12.6 Andere schadelijke effecten.

13. Instructies voor verwijdering

13.1 Afvalverwerkingsmethoden

Afval van residuen / niet-gebruikte producten Verwijderen volgens plaatselijke voorschriften.

Verontreinigde verpakking Lege containers moeten worden afgevoerd naar een erkende afvalverwerkingscentrale voor hergebruik of verwijdering.

14. Informatie met betrekking tot het vervoer

ICAO/IATA niet gereguleerd
14.1.
14.2.
14.3.
14.4.

14.5.
14.6.

15. Regelgeving

15.1 Specifieke veiligheids-, gezondheids- en milieureglementen en -wetgeving voor de stof of het mengsel

Chemische naam	French RG number
Sodium chloride	RG 78

Internationale voorraadlijsten

TSCA	Voldoet aan
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
China	-
AICS	-
KECL	-

Opschrift
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory (Inventaris in Sectie 8(b) van de Amerikaanse wet inzake het beheer van toxische stoffen)
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances (Europese inventaris van bestaande chemische handelsstoffen/Europese lijst van stoffen waarvan kennisgeving is gedaan)
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List (Canadese lijst van chemische stoffen)
PICCS - Philippines Inventory of Chemicals and Chemical Substances (Filippijnse inventaris van chemische stoffen)
ENCS - Japan Inventory of Existing and New Chemical Substances (Japanse inventaris van bestaande en nieuwe chemische stoffen)
IECSC - China Inventory of Existing Chemical Substances (Chinese inventaris van bestaande chemische stoffen)
AICS - Australian Inventory of Chemical Substances (Australische inventaris van chemische stoffen)
KECL - Korean Inventory of Existing and Evaluated Chemical Substances (Koreaanse inventaris van bestaande en beoordeelde chemische stoffen)

15.2 Chemischeveiligheidsbeoordeling

Geen gegevens beschikbaar

16. Overige informatie

Volledige tekst van R-zinnen waarnaar in rubrieken 2 en 3 wordt verwezen
Geen gegevens beschikbaar

Datum van uitgifte	02-aug-2013
Herzieningsdatum	02-aug-2013
Herzieningsnotitie	niet van toepassing.

Dit veiligheidsinformatieblad voldoet aan de eisen van Verordening (EG) Nummer 1907/2006

Vrijwaringclausule
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Einde van het Veiligheidsinformatieblad

SAFETY DATA SHEET

Issuing date 01-Aug-2013 **Revision Date** 01-Aug-2013 **Version** 1

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product code 901012
Product name Para-Pak® Zn-PVA Fixative - CS9012
Contains Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Fixative

1.3 Details of the supplier of the safety data sheet

Manufacturer
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

For further information, please contact:

E-mail Address www.meridianbioscience.com

1.4 Emergency telephone number

Emergency telephone Emergency telephone CHEMTREC (International) 1-800-424-9300/ For US 1-703-527-3887

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Acute oral toxicity	Category 4
Acute inhalation toxicity - gas	Category 4
Acute inhalation toxicity - dust/mist	Category 2
Skin corrosion/irritation	Category 1 Subcategory 1B
Serious eye damage/eye irritation	Category 1
Carcinogenicity	Category 1A
Acute aquatic toxicity	Category 1
Chronic aquatic toxicity	Category 1
Flammable liquids	Category 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

For the full text of the R-phrases mentioned in this Section, see Section 16

Symbol(s)
Xi - Irritant
F - Highly flammable
N - Dangerous for the environment

R-code(s)
F;R11 - Xi;R36 - N;R51/53 - N;R50/53

2.2 Label elements

Signal Word
Danger

Hazard Statements
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
H330 - Fatal if inhaled
H350 - May cause cancer
H410 - Very toxic to aquatic life with long lasting effects
H225 - Highly flammable liquid and vapor
Contains Zinc sulfate, Methyl alcohol, Isopropyl alcohol

Precautionary Statements - EU (§28, 1272/2008)
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower
P280 - Wear eye protection/ face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/ physician
P201 - Obtain special instructions before use
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/ attention
P370 + P378 - In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

2.3 Other information

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

3.2 Mixtures

Chemical Name	EC-No	CAS-No	Weight %	Classification (67/548)	Classification (Reg. 1272/2008)	REACH Registration Number
Ethyl alcohol	200-578-6	64-17-5	25	F; R11	Flam. Liq. 2 (H225)	no data available
Zinc sulfate	231-793-3	7733-02-0	7.9	Xn; R22 Xi; R41 N; R50-53	Acute Tox. 4 (H302) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	no data available
Acetic acid	200-580-7	64-19-7	4.8	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	no data available
Polyvinyl alcohol	-	9002-89-5	4.6	-	no data available	no data available
Glycerin	-	56-81-5	1.9	-	no data available	no data available
Methyl alcohol	Present	67-56-1	1.4	F; R11 T; R23/24/25-39/23/24/25	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	no data available
Isopropyl alcohol	200-661-7	67-63-0	1.4	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	no data available

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Immediate medical attention is required.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek immediate medical attention/advice.

Ingestion Call a physician or Poison Control Center immediately. Immediate medical attention is required. Never give anything by mouth to an unconscious person.

Inhalation Move to fresh air. Get medical attention immediately if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media
CO_2, dry chemical, dry sand, alcohol-resistant foam.

Extinguishing media which shall not be used for safety reasons
No information available.

5.2 Special hazards arising from the substance or mixture

None.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

See Section 12 for additional Ecological Information.

6.2 Environmental precautions

Should not be released into the environment. Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up
Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

6.4 Reference to other sections

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling
Do not breathe vapors or spray mist. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions
Keep containers tightly closed in a cool, well-ventilated place. Keep away from heat and sources of ignition.

7.3 Specific end uses

Other Guidelines
No information available.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	European Union	The United Kingdom	France	Spain	Germany

Ethyl alcohol 64-17-5		STEL: 3000 ppm STEL: 5760 mg/m³ TWA: 1000 ppm TWA: 1920 mg/m³	VME: 1000 ppm VME: 1900 mg/m³ VLCT: 5000 ppm VLCT: 9500 mg/m³	VLA-ED: 1000 ppm VLA-ED: 1910 mg/m³	MAK: 500 ppm MAK: 960 mg/m³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 1920 mg/m³ Skin TWA: 500 ppm TWA: 960 mg/m³
Zinc sulfate 7733-02-0					MAK: 0.1 mg/m³ MAK: 2 mg/m³ Ceiling / Peak: 0.4 mg/m³ Ceiling / Peak: 4 mg/m³
Acetic acid 64-19-7	TWA 10 ppm TWA 25 mg/m³		VLCT: 10 ppm VLCT: 25 mg/m³	VLA-EC: 15 ppm VLA-EC: 37 mg/m³ VLA-ED: 10 ppm VLA-ED: 25 mg/m³	MAK: 10 ppm MAK: 25 mg/m³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³ TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin
Isopropyl alcohol 67-63-0		STEL: 500 ppm STEL: 1250 mg/m³ TWA: 400 ppm TWA: 999 mg/m³	VLCT: 400 ppm VLCT: 980 mg/m³	VLA-EC: 400 ppm VLA-EC: 1000 mg/m³ VLA-ED: 200 ppm VLA-ED: 500 mg/m³	MAK: 200 ppm MAK: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³ TWA: 200 ppm TWA: 500 mg/m³

Component	Italy	Portugal	The Netherlands	Finland	Denmark
Ethyl alcohol 64-17-5 (25)		TWA: 1000 ppm	Skin STEL: 1900 mg/m³ TWA: 260 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Acetic acid 64-19-7 (4.8)		STEL: 15 ppm TWA: 10 ppm		TWA: 5 ppm TWA: 13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³	TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1 (1.4)	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0 (1.4)		STEL: 400 ppm TWA: 200 ppm		TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³	TWA: 200 ppm TWA: 490 mg/m³

Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Ethyl alcohol 64-17-5	STEL 2000 ppm STEL 3800 mg/m³ MAK: 1000 ppm MAK: 1900 mg/m³	STEL: 1000 ppm STEL: 1920 mg/m³ MAK: 500 ppm MAK: 960 mg/m³	NDS: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Zinc sulfate 7733-02-0		STEL: 0.4 mg/m³ STEL: 4 mg/m³ MAK: 0.1 mg/m³ MAK: 2 mg/m³			
Acetic acid 64-19-7	STEL 20 ppm STEL 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	STEL: 20 ppm STEL: 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	NDSCh: 30 mg/m³ NDS: 15 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 20 ppm STEL: 37.5 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 15 ppm STEL: 37 mg/m³

Methyl alcohol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³ Skin	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0	STEL 800 ppm STEL 2000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	STEL: 400 ppm STEL: 1000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	NDSCh: 1200 mg/m³ NDS: 900 mg/m³ Skin	TWA: 100 ppm TWA: 245 mg/m³ STEL: 150 ppm STEL: 306.25 mg/m³	TWA: 200 ppm STEL: 400 ppm Skin

Derived No Effect Level (DNEL) No information available

Predicted No Effect Concentration (PNEC) No information available

8.2 Exposure controls

Engineering Measures Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Eye Protection Tightly fitting safety goggles.

Hand Protection Protective gloves.

Skin and body protection Wear impervious rubber clothing if needed to prevent contact with liquid material.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls Prevent product from entering drains.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	liquid		
Appearance	No information available	**Odor**	No information available
Color	colorless	**Odor Threshold**	No information available

Property	**Values**	**Remarks • Methods**
pH		No information available
Melting/freezing point		No information available
Boiling point/boiling range	85 °C / 185 °F	not applicable
Flash Point	16 °C / 61 °F	not applicable
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Flammability Limits in Air		No information available
upper flammability limit		
lower flammability limit		
Vapor pressure		No information available
Vapor density		No information available
Specific Gravity		No information available
Water solubility		Soluble in water
Solubility in other solvents VALUE		No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Viscosity, kinematic		No information available
Viscosity, dynamic		
Explosive properties	No information available	
Oxidizing Properties	No information available	

9.2 Other information

Softening point	No information available
Molecular Weight	No information available

VOC Content(%)	No information available
Density VALUE	No information available
Bulk Density VALUE	No information available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

10.4 Conditions to Avoid

Heat, flames and sparks.

10.5 Incompatible Materials

Strong bases. Oxidizing agents.

10.6 Hazardous Decomposition Products

None under normal use conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Product Information	Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation	There is no data available for this product.
Eye contact	There is no data available for this product.
Skin contact	There is no data available for this product.
Ingestion	There is no data available for this product.
Acute toxicity	59.5% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	1,339.00 mg/kg
Dermal	4,818.00 mg/kg
Inhalation	
Gas	3,344.00 mg/l
Mist	0.20 mg/l
Vapor	106.70 mg/l

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethyl alcohol	7060 mg/kg (Rat)		124.7 mg/L (Rat) 4 h
Zinc sulfate	500 mg/kg (Rat)		
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h
Methyl alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h 64000 ppm (Rat) 4 h
Isopropyl alcohol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Skin corrosion/irritation No information available.

Eye damage/irritation No information available.

Sensitization No information available.

Germ Cell Mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

Specific target organ systemic toxicity (single exposure) No information available.

Specific target organ systemic toxicity (repeated exposure) No information available.

Aspiration hazard No information available.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Ethyl alcohol		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through >100: 96 h Pimephales promelas mg/L LC50 static	10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static 9268 - 14221: 48 h Daphnia magna mg/L LC50
Zinc sulfate	0.056: 72 h Pseudokirchneriella subcapitata mg/L EC50 static 2.4: 96 h Chlorella vulgaris mg/L EC50 64.8: 72 h Chlorella vulgaris mg/L EC50	0.03-0.05: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.06: 96 h Pimephales promelas mg/L LC50 static 0.15: 96 h Cyprinus carpio mg/L LC50 semi-static 0.162: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 0.168-0.25: 96 h Pimephales promelas mg/L LC50 semi-static 0.218-0.42: 96 h Pimephales promelas mg/L LC50 flow-through 0.23-0.48: 96 h Pimephales promelas mg/L LC50 0.34-0.93: 96 h Oncorhynchus mykiss mg/L LC50 static 0.48-1.72: 96 h Poecilia reticulata mg/L LC50 static 0.63: 96 h Poecilia reticulata mg/L LC50 16.85-27.18: 96 h Cyprinus carpio mg/L LC50 static 3-4.6: 96 h Lepomis macrochirus mg/L LC50 flow-through 3.55-6.32: 96 h Lepomis macrochirus mg/L LC50 static 49.23-64.16: 96 h Poecilia reticulata mg/L LC50 semi-static	0.538 - 0.908: 48 h Daphnia magna mg/L EC50 Static 0.75: 48 h Daphnia magna mg/L EC50
Acetic acid		75: 96 h Lepomis macrochirus mg/L LC50 static 79: 96 h Pimephales promelas mg/L LC50 static	47: 24 h Daphnia magna mg/L EC50 65: 48 h Daphnia magna mg/L EC50 Static

Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Isopropyl alcohol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

Chemical Name	log Pow
Ethyl alcohol	0
Acetic acid	0
Methyl alcohol	-0.77
Isopropyl alcohol	0.05

12.4 Mobility in soil

Mobility
No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste from residues / unused products Dispose of as hazardous waste in compliance with local and national regulations. Should not be released into the environment.

Contaminated packaging Dispose of in accordance with local regulations. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

IATA/DOT Flammable Liquid, Corrosive, n.o.s.
14.1. UN/ID No 2924
14.2. Technical Name Ethanol, Acetic Acid
14.3. Hazard class 3
Subsidiary hazard class 8
14.4. Packing Group II
Description Para-Pak® Zn-PVA
14.5.
IATA Note None

14.6. DOT Note Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Chemical Name	French RG number
Ethyl alcohol	RG 84
Methyl alcohol	RG 84
Isopropyl alcohol	RG 84

International Inventories

TSCA	Complies
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

Legend
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2 Chemical Safety Report

No information available

SECTION 16. OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3
R41 - Risk of serious damage to eyes
R22 - Harmful if swallowed
R35 - Causes severe burns
R10 - Flammable
R11 - Highly flammable
R67 - Vapors may cause drowsiness and dizziness
R36 - Irritating to eyes
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R39/23/24/25 - Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Full text of H-Statements referred to under sections 2 and 3
H314 - Causes severe skin burns and eye damage
H226 - Flammable liquid and vapor
H301 - Toxic if swallowed
H311 - Toxic in contact with skin
H331 - Toxic if inhaled
H370 - Causes damage to organs (a,b,c) if inhaled
H225 - Highly flammable liquid and vapor
H319 - Causes serious eye irritation
H336 - May cause drowsiness or dizziness
H302 - Harmful if swallowed
H318 - Causes serious eye damage
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
H330 - Fatal if inhaled
H350 - May cause cancer
H410 - Very toxic to aquatic life with long lasting effects

Issuing date	01-Aug-2013
Revision Date	01-Aug-2013
Revision Note	not applicable.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Disclaimer
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

SAFETY DATA SHEET

Data dell'edizione 01-ago-2013 **Data di revisione** 01-ago-2013 **Versione** 1

1. Identificazione della sostanza o della miscela e della società/impresa

1.1 Identificatore del prodotto

Codice prodotto 901012
Nome del prodotto Para-Pak® Zn-PVA Fixative - CS9012
contiene Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

1.2 Usi pertinenti identificati della sostanza o miscela e usi sconsigliati

Utilizzi raccomandati Fissativo

1.3 Informazioni sul fornitore della scheda di dati di sicurezza

Fabbricante
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Per ulteriori informazioni, contattare:

Indirizzo e-mail www.meridianbioscience.com

1.4 Numero telefonico di chiamata urgente

Numero telefonico di chiamata urgente Telefono di emergenza CHEMTREC (Internazionale) 1-800-424-9300 / Per gli Stati Uniti 1-703-527-3887

2. Identificazione dei pericoli

2.1 Classificazione della sostanza o della miscela

REGOLAMENTO (CE) N. 1272/2008

Tossicità acuta per via orale	Categoria 4
Tossicità acuta per via inalatoria - gas	Categoria 4
Tossicità acuta per via inalatoria - polvere/nebbia	Categoria 2
Corrosione/irritazione cutanea	Categoria 1 Subcategory 1B
Lesioni oculari gravi/irritazioni oculari gravi	Categoria 1
Cancerogenicità	Categoria 1A
Tossicità acuto per l'ambiente acquatico	Categoria 1
Tossicità cronica per l'ambiente acquatico	Categoria 1
Liquidi infiammabili	Categoria 2

Classificazione secondo le Direttive EU 67/548/CEE o 1999/45/CE
Per il testo completo delle frasi R menzionate in questa sezione, riferirsi alla sezione 16

Simbolo(i)
Xi - Irritante
F - Facilmente infiammabile
N - Pericoloso per l'ambiente

R-code(s)
F;R11 - Xi;R36 - N;R51/53 - N;R50/53

2.2 Informazioni da indicare sull'etichetta

Avvertenza
PERICOLO

Indicazioni di pericolo
H302 - Nocivo se ingerito
H314 - Provoca gravi ustioni cutanee e gravi lesioni oculari
H330 - Letale se inalato.
H350 - Può provocare il cancro
H410 - Molto tossico per gli organismi acquatici con effetti di lunga durata
H225 - Liquido e vapori facilmente infiammabili
contiene Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

Consigli di prudenza
P304 + P340 - IN CASO DI INALAZIONE: trasportare l'infortunato all'aria aperta e mantenerlo a riposo in posizione che favorisca la respirazione
P403 + P233 - Tenere il recipiente ben chiuso e in luogo ben ventilato.
P280 - Indossare guanti/ indumenti protettivi/ Proteggere gli occhi/ il viso.
P260 - Non respirare la polvere o la nebbia
P303 + P361 + P353 - IN CASO DI CONTATTO CON LA PELLE (o con i capelli): togliersi di dosso immediatamente tutti gli indumenti contaminati. Sciacquare la pelle/ fare una doccia.
P280 - Indossare protezione per occhi/ protezione facciale
P305 + P351 + P338 - IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare
P310 - Contattare immediatamente un CENTRO ANTIVELENI o un medico
P201 - Procurarsi istruzioni specifiche prima dell'uso
P281 - Utilizzare il dispositivo di protezione individuale richiesto
P308 + P313 - IN CASO di esposizione o di possibile esposizione, consultare un medico
P370 + P378 - In caso di incendio: Usare sabbia secca, prodotto chimico secco oppure schiuma resistente all'alcool per l'estinzione
P210 - Tenere lontano da fonti di calore/scintille/fiamme libere/superfici riscaldate. - Non fumare.

2.3 Altre informazioni

3. Composizione/informazione sugli ingredienti

3.1 Sostanze

3.2 Miscele

Nome Chimico	N. CE	N. CAS	Percentuale in peso	Classificazione (67/548)	Classificazione (Reg. 1272/2008)	Numero di registrazione REACH
Ethyl alcohol	200-578-6	64-17-5	25	F; R11	Flam. Liq. 2 (H225)	nessun dato disponibile
Zinc sulfate	231-793-3	7733-02-0	7.9	Xn; R22 Xi; R41 N; R50-53	Acute Tox. 4 (H302) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	nessun dato disponibile
Acetic acid	200-580-7	64-19-7	4.8	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	nessun dato disponibile
Polyvinyl alcohol	-	9002-89-5	4.6	-	nessun dato disponibile	nessun dato disponibile
Glycerin	-	56-81-5	1.9	-	nessun dato disponibile	nessun dato disponibile
Methyl alcohol	Present	67-56-1	1.4	F; R11 T; R23/24/25-39/23/24/25	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	nessun dato disponibile
Isopropyl alcohol	200-661-7	67-63-0	1.4	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	nessun dato disponibile

Per il testo completo delle frasi R menzionate in questa sezione, riferirsi alla sezione 16

Per quanto riguarda il testo completo delle dichiarazioni-H menzionate in questo paragrafo, consultare il paragrafo 16

4. Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Contatto con gli occhi Sciacquare immediatamente con molta acqua anche sotto le palpebre, per almeno 15 minuti. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Si richiede un immediato aiuto medico.

Contatto con la pelle Lavare immediatamente con acqua abbondante e sapone togliendo tutti gli indumenti e scarpe contaminati. Richiedere immediadamente un controllo medico/consiglio.

Ingestione Chiamare immediatamente un medico o il centro antiveleni. Si richiede un immediato aiuto medico. Non somministrare alcunchè a persone svenute.

Inalazione Portare all'aria aperta. Consultare immediatamente un medico se si presentano sintomi.

4.2 Principali sintomi ed effetti, sia acuti e che ritardati

4.3 Indicazione per una consultazione medica immediata e per un adeguato trattamento medico speciale

Note per il medico Trattare sintomaticamente.

5. Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione appropriati
CO_2, dry chemical, dry sand, alcohol-resistant foam.

Mezzi di estinzione da non utilizzare per ragioni di sicurezza
Nessuna informazione disponibile.

5.2 Pericoli speciali derivanti dalla sostanza o dalla miscela

Nessuno(a).

5.3 Raccomandazioni per gli addetti all'estinzione degli incendi

In caso di incendio, indossare un apparato di respirazione autonomo e un dispositivo di protezione completo.

6. Misure in caso di fuoriuscita accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure in caso di emergenza

Prevedere una ventilazione adeguata.

Per ulteriori informazioni ecologiche, fare riferimento alla Sezione 12.

6.2 Precauzioni ambientali

Non deve essere abbandonato nell'ambiente. Non scaricare il prodotto nelle fogne. Evitare sversamenti o perdite supplementari, se questo può essere fatto senza pericolo.

6.3 Metodi e materiali per il contenimento e per la bonifica

Metodi di pulizia
Assorbire con terra, sabbia o altro materiale non combustibile e trasferire in contenitori per il successivo smaltimento.

6.4 Riferimenti ad altre sezioni

7. Manipolazione e immagazzinamento

7.1 Precauzioni per la manipolazione sicura

Avvertenze per un impiego sicuro
Non respirare vapori o aerosol. Prevedere una ventilazione adeguata. Evitare il contatto con la pelle, con gli occhi e con gli indumenti. Tenere lontano da fiamme libere, superfici calde e sorgenti di ignizione.

7.2 Condizioni per lo stoccaggio sicuro, comprese eventuali incompatibilità

Misure tecniche/Modalità d'immagazzinaggio
Tenere i contenitori ermeticamente chiusi in un ambiente fresco e ben ventilato. Tenere lontano da fonti di calore e altre cause d'incendio.

7.3 Usi finali particolari

Altre guide di riferimento
Nessuna informazione disponibile.

8. Controllo dell'esposizione/protezione individuale

8.1 Parametri di controllo

Limiti di esposizione Questo prodotto, come viene fornito, non contiene alcuna sostanza pericolosa in base ai limiti di esposizione sul luogo di lavoro stabiliti dagli enti normativi specifici del paese

Nome Chimico	Unione Europea	Il Regno Unito	Francia	Spagna	Germania
Ethyl alcohol 64-17-5		STEL: 3000 ppm STEL: 5760 mg/m³ TWA: 1000 ppm TWA: 1920 mg/m³	VME: 1000 ppm VME: 1900 mg/m³ VLCT: 5000 ppm VLCT: 9500 mg/m³	VLA-ED: 1000 ppm VLA-ED: 1910 mg/m³	MAK: 500 ppm MAK: 960 mg/m³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 1920 mg/m³ Skin TWA: 500 ppm TWA: 960 mg/m³
Zinc sulfate 7733-02-0					MAK: 0.1 mg/m³ MAK: 2 mg/m³ Ceiling / Peak: 0.4 mg/m³ Ceiling / Peak: 4 mg/m³
Acetic acid 64-19-7	TWA 10 ppm TWA 25 mg/m³		VLCT: 10 ppm VLCT: 25 mg/m³	VLA-EC: 15 ppm VLA-EC: 37 mg/m³ VLA-ED: 10 ppm VLA-ED: 25 mg/m³	MAK: 10 ppm MAK: 25 mg/m³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³ TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin
Isopropyl alcohol 67-63-0		STEL: 500 ppm STEL: 1250 mg/m³ TWA: 400 ppm TWA: 999 mg/m³	VLCT: 400 ppm VLCT: 980 mg/m³	VLA-EC: 400 ppm VLA-EC: 1000 mg/m³ VLA-ED: 200 ppm VLA-ED: 500 mg/m³	MAK: 200 ppm MAK: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³ TWA: 200 ppm TWA: 500 mg/m³

Component	Italia	Portogallo	i Paesi Bassi	Finlandia	Danimarca
Ethyl alcohol 64-17-5 (25)		TWA: 1000 ppm	Skin STEL: 1900 mg/m³ TWA: 260 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Acetic acid 64-19-7 (4.8)		STEL: 15 ppm TWA: 10 ppm		TWA: 5 ppm TWA: 13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³	TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1 (1.4)	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0 (1.4)		STEL: 400 ppm TWA: 200 ppm		TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³	TWA: 200 ppm TWA: 490 mg/m³

Nome Chimico	Austria	Svizzera	Polonia	Norvegia	Irlanda
Ethyl alcohol 64-17-5	STEL 2000 ppm STEL 3800 mg/m³ MAK: 1000 ppm MAK: 1900 mg/m³	STEL: 1000 ppm STEL: 1920 mg/m³ MAK: 500 ppm MAK: 960 mg/m³	NDS: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Zinc sulfate 7733-02-0		STEL: 0.4 mg/m³ STEL: 4 mg/m³ MAK: 0.1 mg/m³ MAK: 2 mg/m³			
Acetic acid 64-19-7	STEL 20 ppm STEL 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	STEL: 20 ppm STEL: 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	NDSCh: 30 mg/m³ NDS: 15 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 20 ppm STEL: 37.5 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 15 ppm STEL: 37 mg/m³

Methyl alcohol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³ Skin	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0	STEL 800 ppm STEL 2000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	STEL: 400 ppm STEL: 1000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	NDSCh: 1200 mg/m³ NDS: 900 mg/m³ Skin	TWA: 100 ppm TWA: 245 mg/m³ STEL: 150 ppm STEL: 306.25 mg/m³	TWA: 200 ppm STEL: 400 ppm Skin

Livello derivato senza effetto (DNEL) Nessuna informazione disponibile

La concentrazione prevedibile senza effetto (PNEC) Nessuna informazione disponibile

8.2 Controlli dell'esposizione

Dati di progetto Assicurare un'adeguata areazione, specialmente in zone chiuse.

Protezione individuale

Protezione degli occhi Occhiali di sicurezza ben aderenti.

Protezione delle mani Guanti di protezione.

Protezione della pelle e del corpo Wear impervious rubber clothing if needed to prevent contact with liquid material.

Protezione respiratoria Quando si verificano concentrazioni superiori ai limiti di esposizione, è obbligatorio l'uso di adeguati sistemi di protezione delle vie respiratorie.

Misure di igiene Manipolare rispettando le buone pratiche di igiene industriale e di sicurezza adeguate.

Controlli dell'esposizione ambientale Non scaricare il prodotto nelle fogne.

9. Proprietà fisiche e chimiche

9.1 Informazioni sulle proprietà fisiche e chimiche fondamentali

Stato fisico	Liquido		
Aspetto	Nessuna informazione disponibile	**Odore**	Nessuna informazione disponibile
Colore	incolore	**Soglia di odore**	Nessuna informazione disponibile

Proprietà	**Valori**	**Osservazioni • Methods**
pH		Nessuna informazione disponibile
Punto di fusione/congelamento		Nessuna informazione disponibile
Punto/intervallo di ebollizione	85 °C / 185 °F	non applicabile
Punto di infiammabilità	16 °C / 61 °F	non applicabile
Tasso di evaporazione		Nessuna informazione disponibile
Infiammabilità (solidi, gas)		Nessuna informazione disponibile
Limiti d' infiammabilità nell'aria		Nessuna informazione disponibile
Limite superiore di infiammabilità		
limite inferiore di infiammabilità		
Pressione di vapore		Nessuna informazione disponibile
Densità di vapore		Nessuna informazione disponibile
Densità relativa		Nessuna informazione disponibile
Idrosolubilità		Solubile in acqua
Solubilità in altri solventi		Nessuna informazione disponibile
Coefficiente di ripartizione: n-ottanolo/acqua		Nessuna informazione disponibile
Temperatura di autoaccensione		Nessuna informazione disponibile
Temperatura di decomposizione		Nessuna informazione disponibile
Viscosità, cinematica		Nessuna informazione disponibile
Viscosità, dinamica		
Proprietà esplosive	Nessuna informazione disponibile	

Proprietà ossidanti	Nessuna informazione disponibile

9.2 Altre informazioni

Punto di rammollimento	Nessuna informazione disponibile
Peso Molecolare	Nessuna informazione disponibile
Tenore di VOC (composti organici volatili)	Nessuna informazione disponibile
Densità	Nessuna informazione disponibile
Densità Apparente	Nessuna informazione disponibile

10. Stabilità e reattività

10.1 Reattività

10.2 Stabilità chimica

Stabile in condizioni normali.

10.3 Possibilità di reazioni pericolose

10.4 Condizioni da evitare

Calore, fiamme e scintille.

10.5 Materiali incompatibili

Basi forti. Agenti ossidanti.

10.6 Prodotti di decomposizione pericolosi

Nessuno in condizioni normali d'uso.

11. INFORMAZIONI TOSSICOLOGICHE

11.1 Informazioni sugli effetti tossicologici

Tossicità acuta

Informazioni sul prodotto	Il prodotto non presenta alcun pericolo di tossicità acuta, in base alle informazioni fornite o note.
Inalazione	Non vi sono dati disponibili per questo prodotto.
Contatto con gli occhi	Non vi sono dati disponibili per questo prodotto.
Contatto con la pelle	Non vi sono dati disponibili per questo prodotto.
Ingestione	Non vi sono dati disponibili per questo prodotto.
Tossicità acuta	59.5% della miscela consiste di un ingrediente (i) di tossicità sconosciuta.

The following values are calculated based on chapter 3.1 of the GHS document:

Orale	1,339.00 mg/kg
Dermico	4,818.00 mg/kg
Inalazione	
gas	3,344.00 mg/l
Nebbia	0.20 mg/l
Vapori	106.70 mg/l

Nome Chimico	LD50 Orale	LD50 Dermico	CL50 Inalazione

Ethyl alcohol	7060 mg/kg (Rat)		124.7 mg/L (Rat) 4 h
Zinc sulfate	500 mg/kg (Rat)		
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h
Methyl alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h 64000 ppm (Rat) 4 h
Isopropyl alcohol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Corrosione/irritazione cutanea Nessuna informazione disponibile.

Danno agli occhi/irritazione Nessuna informazione disponibile.

Sensibilizzazione Nessuna informazione disponibile.

Mutagenicità sulle cellule germinali Nessuna informazione disponibile.

Cancerogenicità Nessuna informazione disponibile.

Tossicità per la riproduzione Nessuna informazione disponibile.

Tossicità specifica per organi bersaglio - esposizione singola Nessuna informazione disponibile.

Tossicità specifica per organi bersaglio - esposizione ripetuta Nessuna informazione disponibile.

Pericolo in caso di aspirazione Nessuna informazione disponibile.

12. Informazioni ecologiche

12.1 Tossicità

Effetti legati all'ecotossicità Tossico per gli organismi acquatici, può provocare a lungo termine effetti negativi per l'ambiente acquatico.

Nome Chimico	Tossicità per le alghe	Tossicità per i pesci	Tossicità per la daphnia e per altri invertebrati acquatici
Ethyl alcohol		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through >100: 96 h Pimephales promelas mg/L LC50 static	10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static 9268 - 14221: 48 h Daphnia magna mg/L LC50

Zinc sulfate	0.056: 72 h Pseudokirchneriella subcapitata mg/L EC50 static 2.4: 96 h Chlorella vulgaris mg/L EC50 64.8: 72 h Chlorella vulgaris mg/L EC50	0.03-0.05: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.06: 96 h Pimephales promelas mg/L LC50 static 0.15: 96 h Cyprinus carpio mg/L LC50 semi-static 0.162: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 0.168-0.25: 96 h Pimephales promelas mg/L LC50 semi-static 0.218-0.42: 96 h Pimephales promelas mg/L LC50 flow-through 0.23-0.48: 96 h Pimephales promelas mg/L LC50 0.34-0.93: 96 h Oncorhynchus mykiss mg/L LC50 static 0.48-1.72: 96 h Poecilia reticulata mg/L LC50 static 0.63: 96 h Poecilia reticulata mg/L LC50 16.85-27.18: 96 h Cyprinus carpio mg/L LC50 static 3-4.6: 96 h Lepomis macrochirus mg/L LC50 flow-through 3.55-6.32: 96 h Lepomis macrochirus mg/L LC50 static 49.23-64.16: 96 h Poecilia reticulata mg/L LC50 semi-static	0.538 - 0.908: 48 h Daphnia magna mg/L EC50 Static 0.75: 48 h Daphnia magna mg/L EC50
Acetic acid		75: 96 h Lepomis macrochirus mg/L LC50 static 79: 96 h Pimephales promelas mg/L LC50 static	47: 24 h Daphnia magna mg/L EC50 65: 48 h Daphnia magna mg/L EC50 Static
Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Isopropyl alcohol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50

12.2 Persistenza e degradabilità

Nessuna informazione disponibile.

12.3 Potenziale di bioaccumulazione

Nessuna informazione disponibile.

Nome Chimico	log Pow
Ethyl alcohol	0
Acetic acid	0
Methyl alcohol	-0.77
Isopropyl alcohol	0.05

12.4 Mobilità nel suolo

Mobilità
Nessuna informazione disponibile.

12.5 Risultati della valutazione PBT e vpvb

Nessuna informazione disponibile.

12.6 Altri effetti nocivi.

13. Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti dagli scarti / prodotti inutilizzati	Eliminare come rifiuto pericoloso rispettando i regolamenti locali e nazionali. Non deve essere abbandonato nell'ambiente.
Contenitori contaminati	Eliminare nel rispetto della normativa vigente in materia. Non riutilizzare contenitori vuoti.

14. Informazioni sul trasporto

ICAO/IATA	Flammable Liquid, Corrosive, n.o.s.
14.1. UN/ID N	2924
14.2. Nome di spedizione appropriato ONU	Ethanol, Acetic Acid
14.3. Classe di pericolo	3
Classe di pericolo sussidiario	8
14.4. Gruppo d'imballaggio	II
Descrizione	Para-Pak® Zn-PVA
14.5. Disposizioni speciali	nessuno(a)
14.6. Nota	Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

15. Informazioni sulla regolamentazione

15.1 Norme e legislazione su salute, sicurezza e ambiente specifiche per la sostanza o la miscela

Nome Chimico	French RG number
Ethyl alcohol	RG 84
Methyl alcohol	RG 84
Isopropyl alcohol	RG 84

Inventari internazionali

TSCA	Attenente a
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
Cina	-
AICS	-
KECL	-

Legenda
TSCA – Inventario del Toxic Substances Control Act degli Stati Uniti, sezione 8(b)
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances (Inventario europeo delle sostanze chimiche esistenti a carattere commerciale /Lista europea delle sostanze chimiche notificate)
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List (Lista delle sostanze nazionali del Canada/ Lista delle sostanze non nazionali)
PICCS - Philippines Inventory of Chemicals and Chemical Substances (Inventario delle sostanze chimiche delle Filippine)
ENCS - Japan Existing and New Chemical Substances (Sostanze chimiche nuove ed esistenti in Giappone)
IECSC - China Inventory of Existing Chemical Substances (Inventario cinese delle sostanze chimiche esistenti)
AICS - Inventario Australiano di Sostanze Chimiche
\b KECL - Korean Existing and Evaluated Chemical Substances (Sostanze chimiche esistenti e valutate in Corea)

15.2 Valutazione della sicurezza chimica

Nessuna informazione disponibile

16. Altre informazioni

Testo integrale delle frasi R citate nei Capitoli 2 e 3
R41 - Rischio di gravi lesioni oculari
R22 - Nocivo per ingestione
R35 - Provoca gravi ustioni
R10 - Infiammabile
R11 - Facilmente infiammabile
R67 - L'inalazione dei vapori può provocare sonnolenza e vertigini
R36 - Irritante per gli occhi
R50/53 - Altamente tossico per gli organismi acquatici, può provocare a lungo termine effetti negativi per l'ambiente acquatico
R39/23/24/25 - Tossico: pericolo di effetti irreversibili molto gravi per inalazione, a contatto con la pelle e per ingestione
R23/24/25 - Tossico per inalazione, contatto con la pelle e per ingestione
R51/53 - Tossico per gli organismi acquatici, può provocare a lungo termine effetti negativi per l'ambiente acquatico

Riferimenti a Dichiarazioni-H sotto forma di testo completo sotto i paragrafi 2 e 3
H314 - Provoca gravi ustioni cutanee e gravi lesioni oculari
H226 - Liquido e vapori infiammabili
H301 - Tossico se ingerito
H311 - Tossico per contatto con la pelle
H331 - Tossico se inalato
H370 - Provoca danni agli organi (a,b,c) se inalato
H225 - Liquido e vapori facilmente infiammabili
H319 - Provoca grave irritazione oculare
H336 - Può provocare sonnolenza o vertigini
H302 - Nocivo se ingerito
H318 - Provoca gravi lesioni oculari
H400 - Molto tossico per gli organismi acquatici
H410 - Molto tossico per gli organismi acquatici con effetti di lunga durata
H302 - Nocivo se ingerito
H314 - Provoca gravi ustioni cutanee e gravi lesioni oculari
H330 - Letale se inalato.
H350 - Può provocare il cancro
H410 - Molto tossico per gli organismi acquatici con effetti di lunga durata

Data dell'edizione	01-ago-2013
Data di revisione	01-ago-2013
Nota di Revisione	non applicabile.

Questa scheda di sicurezza rispetta le prescrizioni del Regolamento (CE) Num. 1907/2006

Diniego
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Fine della Scheda Sicurezza Prodotto

FICHE DE DONNÉES DE SÉCURITÉ.

Date d'émission 01-août-2013 **Date de révision** 01-août-2013 **Version** 1

SECTION 1. Identification de la substance/du mélange et de la société/l'entreprise

1.1 Identificateur de produit

Code du produit 901012
Nom du produit Para-Pak® Zn-PVA Fixative - CS9012
Contient Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

1.2 Utilisations identifiées pertinentes de la substance ou du mélange et utilisations déconseillées

Utilisation recommandée Fixateur

1.3 Renseignements concernant le fournisseur de la fiche de données de sécurité

Fabricant
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Pour plus d'informations, veuillez prendre contact avec:

Adresse e-mail www.meridianbioscience.com

1.4 Numéro d'appel d'urgence

Numéro de téléphone d'appel d'urgence: Téléphone d'urgence CHEMTREC (International) 1-800-424-9300 / 1-703-527-3887 Pour américain

SECTION 2. Identification des dangers

2.1 Classification de la substance ou du mélange

RÈGLEMENT (CE) No 1272/2008

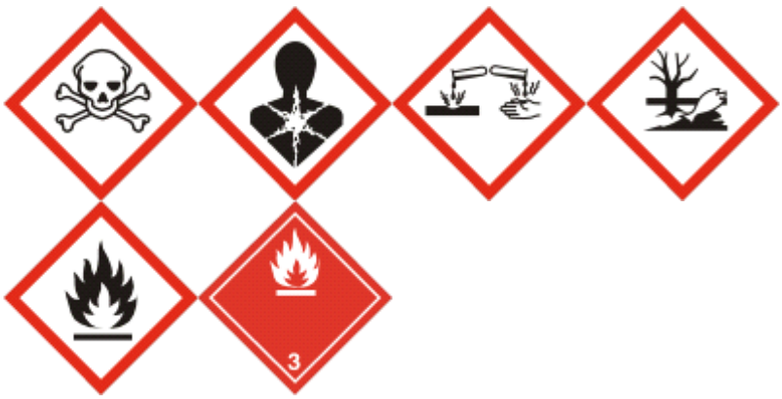
Toxicité aiguë par voie orale	Catégorie 4
Toxicité aiguë par inhalation - gaz	Catégorie 4
Toxicité aiguë par inhalation - poussières/brouillard	Catégorie 2
Corrosion cutanée/irritation cutanée	Catégorie 1 Subcategory 1B
Lésions oculaires graves/irritation oculaire	Catégorie 1
Cancérogénicité	Catégorie 1A
Toxicité aiguë pour le milieu aquatique	Catégorie 1
Toxicité chronique pour le milieu aquatique	Catégorie 1
Liquides inflammables	Catégorie 2

Classification conformément aux Directives UE 67/548/CEE ou 1999/45/CE
Pour le texte complet des Phrases-R mentionnées dans ce chapitre, voir section 16

Symbole(s)
Xi - Irritant
F - Facilement inflammable
N - Dangereux pour l'environnement

R-code(s)
F;R11 - Xi;R36 - N;R51/53 - N;R50/53

2.2 Éléments d'étiquetage



Mention d'avertissement
DANGER

Mentions de danger
H302 - Nocif en cas d'ingestion
H314 - Provoque des brûlures de la peau et des lésions oculaires graves
H330 - Mortel par inhalation.
H350 - Peut provoquer le cancer
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
H225 - Liquide et vapeurs très inflammables
Contient Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

Conseils de prudence
P304 + P340 - EN CAS D'INHALATION: transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer
P403 + P233 - Stocker dans un endroit bien ventilé. Maintenir le récipient fermé de manière étanche.
P280 - Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/ du visage.
P260 - Ne pas respirer les poussières ou brouillards
P303 + P361 + P353 - EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): enlever immédiatement les vêtements contaminés. Rincer la peau à l'eau/ se doucher.
P280 - Porter un équipement de protection des yeux/ du visage
P305 + P351 + P338 - EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer
P310 - Appeler immédiatement un CENTRE ANTIPOISON ou un médecin
P201 - Se procurer les instructions avant utilisation
P281 - Utiliser l'équipement de protection individuel requis
P308 + P313 - EN CAS d'exposition prouvée ou suspectée: consulter un médecin
P370 + P378 - En cas d'incendie: Utiliser du sable sec, de la poudre chimique sèche ou de la mousse résistant à l'alcool pour l'extinction
P210 - Tenir à l'écart de la chaleur/des étincelles/des flammes nues/des surfaces chaudes. - Ne pas fumer.

2.3 Autres informations

SECTION 3. Composition/informations sur les composants

3.1 Substances

3.2 Mélanges

Nom Chimique	No.-CE	No.-CAS	Pour cent en poids	Classification (67/548)	Classification (Règ. 1272/2008)	Numéro d'Enregistrement REACH
Ethyl alcohol	200-578-6	64-17-5	25	F; R11	Flam. Liq. 2 (H225)	donnée non disponible
Zinc sulfate	231-793-3	7733-02-0	7.9	Xn; R22 Xi; R41 N; R50-53	Acute Tox. 4 (H302) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	donnée non disponible
Acetic acid	200-580-7	64-19-7	4.8	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	donnée non disponible
Polyvinyl alcohol	-	9002-89-5	4.6	-	donnée non disponible	donnée non disponible
Glycerin	-	56-81-5	1.9	-	donnée non disponible	donnée non disponible
Methyl alcohol	Present	67-56-1	1.4	F; R11 T; R23/24/25-39/23/24/25	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	donnée non disponible
Isopropyl alcohol	200-661-7	67-63-0	1.4	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	donnée non disponible

Pour le texte complet des Phrases-R mentionnées dans ce chapitre, voir section 16

Pour le texte complet des Phrases-H mentionnées dans ce chapitre, voir section 16

SECTION 4. Premiers secours

4.1 Description des premiers secours

Contact avec les yeux Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Un examen médical immédiat est requis.

Contact avec la peau Laver immédiatement au savon et abondamment à l'eau en enlevant les vêtements contaminés et les chaussures. Consulter immédiatement un médecin.

Ingestion Appeler immédiatement un médecin ou un centre AntiPoison. Un examen médical immédiat est requis. Ne jamais rien faire avaler à une personne inconsciente.

Inhalation Amener la victime à l'air libre. Faire immédiatement appel à une assistance médicale si des symptômes apparaissent.

4.2 Principaux symptômes et effets, aigus et différés

4.3 Indications quant à une prise en charge médicale immédiate ou d'un traitement spécial

Avis aux médecins Traiter de façon symptomatique.

SECTION 5. Mesures de lutte contre l'incendie

5.1 Moyens d'extinction

Moyens d'extinction appropriés
CO_2, dry chemical, dry sand, alcohol-resistant foam.

Moyen d'extinction à ne pas utiliser pour des raisons de sécurité
Pas d'information disponible.

5.2 Dangers particuliers résultant de la substance ou du mélange

aucun(e).

5.3 Conseils aux pompiers

Comme lors de tout incendie, porter un équipement respiratoire autonome et un équipement complet de protection.

SECTION 6. Mesures à prendre en cas de dispersion accidentelle

6.1 Précautions individuelles, équipement de protection et procédures d'urgence

Assurer une ventilation adéquate.

Voir la Rubrique 12 pour des informations supplémentaires sur les effets écologiques.

6.2 Précautions pour la protection de l'environnement

Ne pas décharger dans l'environnement. Éviter que le produit arrive dans les égouts. Éviter un déversement ou une fuite supplémentaire, si cela est possible sans danger.

6.3 Méthodes et matériel de confinement et de nettoyage

Méthodes de nettoyage
Absorber avec de la terre, du sable ou un autre matériau non combustible et transférer dans des récipients pour élimination ultérieure.

6.4 Référence à d'autres sections

SECTION 7. Manipulation et stockage

7.1 Précautions à prendre pour une manipulation sans danger

Conseils pour une manipulation sans danger
Ne pas respirer les vapeurs ou le brouillard de pulvérisation. Assurer une ventilation adéquate. Éviter le contact avec la peau, les yeux et les vêtements. Tenir à l'abri des flammes nues, des surfaces chaudes et des sources d'inflammation.

7.2 Conditions d'un stockage sûr, y compris d'éventuelles incompatibilités

Mesures techniques/Conditions de stockage
Tenir les récipients bien fermés dans un endroit frais et bien aéré. Tenir à l'écart de la chaleur et des sources d'ignition.

7.3 Utilisation(s) finale(s) particulière(s)

Autres lignes directrices
Pas d'information disponible.

SECTION 8. Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

Limites d'exposition Ce produit tel qu'expédié ne contient pas de substance dangereuse dont les limites d'exposition professionnelle auraient été établies par les organismes de régulation locaux

Nom Chimique	Union Européenne	Royaume Uni	France	Espagne	Allemagne
Ethyl alcohol 64-17-5		STEL: 3000 ppm STEL: 5760 mg/m³ TWA: 1000 ppm TWA: 1920 mg/m³	VME: 1000 ppm VME: 1900 mg/m³ VLCT: 5000 ppm VLCT: 9500 mg/m³	VLA-ED: 1000 ppm VLA-ED: 1910 mg/m³	MAK: 500 ppm MAK: 960 mg/m³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 1920 mg/m³ Skin TWA: 500 ppm TWA: 960 mg/m³
Zinc sulfate 7733-02-0					MAK: 0.1 mg/m³ MAK: 2 mg/m³ Ceiling / Peak: 0.4 mg/m³ Ceiling / Peak: 4 mg/m³
Acetic acid 64-19-7	TWA 10 ppm TWA 25 mg/m³		VLCT: 10 ppm VLCT: 25 mg/m³	VLA-EC: 15 ppm VLA-EC: 37 mg/m³ VLA-ED: 10 ppm VLA-ED: 25 mg/m³	MAK: 10 ppm MAK: 25 mg/m³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³ TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin
Isopropyl alcohol 67-63-0		STEL: 500 ppm STEL: 1250 mg/m³ TWA: 400 ppm TWA: 999 mg/m³	VLCT: 400 ppm VLCT: 980 mg/m³	VLA-EC: 400 ppm VLA-EC: 1000 mg/m³ VLA-ED: 200 ppm VLA-ED: 500 mg/m³	MAK: 200 ppm MAK: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³ TWA: 200 ppm TWA: 500 mg/m³

Component	Italie	Portugal	Pays-Bas	Finlande	Danemark
Ethyl alcohol 64-17-5 (25)		TWA: 1000 ppm	Skin STEL: 1900 mg/m³ TWA: 260 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Acetic acid 64-19-7 (4.8)		STEL: 15 ppm TWA: 10 ppm		TWA: 5 ppm TWA: 13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³	TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1 (1.4)	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0 (1.4)		STEL: 400 ppm TWA: 200 ppm		TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³	TWA: 200 ppm TWA: 490 mg/m³

Nom Chimique	Autriche	Suisse	Pologne	Norvège	Irlande
Ethyl alcohol 64-17-5	STEL 2000 ppm STEL 3800 mg/m³ MAK: 1000 ppm MAK: 1900 mg/m³	STEL: 1000 ppm STEL: 1920 mg/m³ MAK: 500 ppm MAK: 960 mg/m³	NDS: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Zinc sulfate 7733-02-0		STEL: 0.4 mg/m³ STEL: 4 mg/m³ MAK: 0.1 mg/m³ MAK: 2 mg/m³			
Acetic acid 64-19-7	STEL 20 ppm STEL 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	STEL: 20 ppm STEL: 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	NDSCh: 30 mg/m³ NDS: 15 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 20 ppm STEL: 37.5 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 15 ppm STEL: 37 mg/m³

Methyl alcohol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³ Skin	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0	STEL 800 ppm STEL 2000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	STEL: 400 ppm STEL: 1000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	NDSCh: 1200 mg/m³ NDS: 900 mg/m³ Skin	TWA: 100 ppm TWA: 245 mg/m³ STEL: 150 ppm STEL: 306.25 mg/m³	TWA: 200 ppm STEL: 400 ppm Skin

Dose dérivée sans effet (DNEL) Pas d'information disponible

Concentration prévisible sans effet (PNEC) Pas d'information disponible

8.2 Contrôles de l'exposition

Mesures d'ordre technique Assurer une ventilation adéquate, surtout dans les endroits clos.

Équipement de protection individuelle

Protection des yeux Lunettes de sécurité à protection intégrale.

Protection des mains Gants de protection.

Protection de la peau et du corps Wear impervious rubber clothing if needed to prevent contact with liquid material.

Protection respiratoire Lorsque les travailleurs sont confrontés à des concentrations supérieures aux limites d'exposition, ils doivent porter des masques appropriés et agréés.

Mesures d'hygiène À manipuler conformément aux bonnes pratiques d'hygiène industrielle et aux consignes de sécurité.

Contrôles d'exposition liés à la protection de l'environnement Éviter que le produit arrive dans les égouts.

SECTION 9. Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques essentielles

État physique	liquide		
Aspect	Pas d'information disponible	**Odeur**	Pas d'information disponible
Couleur	incolore	**Seuil olfactif**	Pas d'information disponible

Propriété	**Valeurs**	**Remarques • Methods**
pH		Pas d'information disponible
Point de fusion/point de congélation		Pas d'information disponible
Point/intervalle d'ébullition	85 °C / 185 °F	non applicable
Point d'éclair	16 °C / 61 °F	non applicable
Taux d'évaporation		Pas d'information disponible
Inflammabilité (solide, gaz)		Pas d'information disponible
Limites d'inflammabilité dans l'air		Pas d'information disponible
limite d'inflammabilité supérieure		
limite d'inflammabilité inférieure		
Pression de vapeur		Pas d'information disponible
Densité de vapeur		Pas d'information disponible
Densité		Pas d'information disponible
Hydrosolubilité		Soluble dans l'eau
Solubilité ds solvant - VALEUR		Pas d'information disponible
Coefficient de partage: n-octanol/eau		Pas d'information disponible
Température d'auto-inflammabilité		Pas d'information disponible
Température de décomposition		Pas d'information disponible

Viscosité, cinématique	Pas d'information disponible
Viscosité, dynamique	
Propriétés explosives	Pas d'information disponible
Propriétés comburantes	Pas d'information disponible

9.2 Autres informations

Point de ramollissement	Pas d'information disponible
Poids moléculaire	Pas d'information disponible
Teneur (%) en COV (composés organiques volatils)	Pas d'information disponible
Masse volumique VALEUR	Pas d'information disponible
Masse volumique apparente VALEUR	Pas d'information disponible

SECTION 10. Stabilité et réactivité

10.1 Réactivité

10.2 Stabilité chimique

Stable dans des conditions normales.

10.3 Possibilité de réactions dangereuses

10.4 Conditions à éviter

Chaleur, flammes et étincelles.

10.5 Matières incompatibles

Des bases fortes. Oxydants.

10.6 Produits de décomposition dangereux

Aucun(e)(s) dans les conditions normales d'utilisation.

11. Informations toxicologiques

11.1 Informations sur les effets toxicologiques

Toxicité aiguë

Informations sur le produit	Le produit ne présente pas de danger de toxicité aiguë d'après les informations connues ou divulguées le concernant.
Inhalation	Il n'y a pas d'informations disponibles pour ce produit.
Contact avec les yeux	Il n'y a pas d'informations disponibles pour ce produit.
Contact avec la peau	Il n'y a pas d'informations disponibles pour ce produit.
Ingestion	Il n'y a pas d'informations disponibles pour ce produit.
Toxicité aiguë	59.5% du mélange consiste en composant(s) dont la toxicité n'est pas connue.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral(e)	1,339.00 mg/kg
Dermale	4,818.00 mg/kg
Inhalation	
gaz	3,344.00 mg/l
Brouillard	0.20 mg/l

vapeur 106.70 mg/l

Nom Chimique	DL50 oral	DL50 dermal	CL50 par inhalation
Ethyl alcohol	7060 mg/kg (Rat)		124.7 mg/L (Rat) 4 h
Zinc sulfate	500 mg/kg (Rat)		
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h
Methyl alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h 64000 ppm (Rat) 4 h
Isopropyl alcohol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Corrosion cutanée/irritation cutanée Pas d'information disponible.

Dommage/irritation de l'œil Pas d'information disponible.

Sensibilisation Pas d'information disponible.

Mutagénicité sur les cellules germinales Pas d'information disponible.

Cancérogénicité Pas d'information disponible.

Toxicité pour la reproduction Pas d'information disponible.

Toxicité spécifique pour certains organes cibles - exposition unique Pas d'information disponible.

Toxicité spécifique pour certains organes cibles - exposition répétée Pas d'information disponible.

Danger par aspiration Pas d'information disponible.

SECTION 12. Informations écologiques

12.1 Toxicité

Effets écotoxicologiques Toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.

Nom Chimique	Toxicité pour les algues	Toxicité pour le poisson	Toxicité pour la daphnie et les autres invertébrés aquatiques
Ethyl alcohol		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through >100: 96 h Pimephales promelas mg/L LC50 static	10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static 9268 - 14221: 48 h Daphnia magna mg/L LC50

Zinc sulfate	0.056: 72 h Pseudokirchneriella subcapitata mg/L EC50 static 2.4: 96 h Chlorella vulgaris mg/L EC50 64.8: 72 h Chlorella vulgaris mg/L EC50	0.03-0.05: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.06: 96 h Pimephales promelas mg/L LC50 static 0.15: 96 h Cyprinus carpio mg/L LC50 semi-static 0.162: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 0.168-0.25: 96 h Pimephales promelas mg/L LC50 semi-static 0.218-0.42: 96 h Pimephales promelas mg/L LC50 flow-through 0.23-0.48: 96 h Pimephales promelas mg/L LC50 0.34-0.93: 96 h Oncorhynchus mykiss mg/L LC50 static 0.48-1.72: 96 h Poecilia reticulata mg/L LC50 static 0.63: 96 h Poecilia reticulata mg/L LC50 16.85-27.18: 96 h Cyprinus carpio mg/L LC50 static 3-4.6: 96 h Lepomis macrochirus mg/L LC50 flow-through 3.55-6.32: 96 h Lepomis macrochirus mg/L LC50 static 49.23-64.16: 96 h Poecilia reticulata mg/L LC50 semi-static	0.538 - 0.908: 48 h Daphnia magna mg/L EC50 Static 0.75: 48 h Daphnia magna mg/L EC50
Acetic acid		75: 96 h Lepomis macrochirus mg/L LC50 static 79: 96 h Pimephales promelas mg/L LC50 static	47: 24 h Daphnia magna mg/L EC50 65: 48 h Daphnia magna mg/L EC50 Static
Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Isopropyl alcohol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50

12.2 Persistance et dégradabilité

Pas d'information disponible.

12.3 Potentiel de bioaccumulation

Pas d'information disponible.

Nom Chimique	log Pow
Ethyl alcohol	0
Acetic acid	0
Methyl alcohol	-0.77
Isopropyl alcohol	0.05

12.4 Mobilité dans le sol

Mobilité
Pas d'information disponible.

12.5 Résultats des évaluations PBT et VPVB

Pas d'information disponible.

12.6 Autres effets néfastes.

SECTION 13. Considérations relatives à l'élimination

13.1 Méthodes de traitement des déchets

Déchets de résidus / produits non utilisés Éliminer les déchets dangereux en conformité avec les réglementations locales et nationales. Ne pas décharger dans l'environnement.

Emballages contaminés Eliminer le produit conformément à la réglementation locale en vigueur. Ne pas réutiliser des récipients vides.

SECTION 14. Informations relatives au transport

ICAO/IATA Flammable Liquid, Corrosive, n.o.s.
14.1. UN/ID No 2924
14.2. Nom d'expédition des Nations unies Ethanol, Acetic Acid
14.3. Classe de danger 3
Classe de danger subsidiaire 8
14.4. Groupe d'emballage II
Description Para-Pak® Zn-PVA
14.5. Dispositions spéciales Aucun(e)
14.6. Note Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

SECTION 15. Informations réglementaires

15.1 Réglementations/législation particulières à la substance ou au mélange en matière de sécurité, de santé et d'environnement

Nom Chimique	tableaux du régime général
Ethyl alcohol	RG 84
Methyl alcohol	RG 84
Isopropyl alcohol	RG 84

Inventaires internationales

TSCA Est conforme à (aux)
EINECS/ELINCS -
DSL/NDSL -
PICCS -
ENCS -
Chine -
AICS -
KECL -

Légende
TSCA - Loi américaine sur le contrôle des substances toxiques, inventaire, rubrique 8(b)
EINECS/ELINCS – Inventaire européen des substances chimiques commerciales existantes/Liste européenne des substances chimiques notifiées
DSL/NDSL - Liste canadienne des substances domestiques/Liste canadienne des substances non domestiques
PICCS - Inventaire philippin des substances et produits chimiques
ENCS - Liste japonaise des substances chimiques existantes et nouvelles
IECSC - Inventaire chinois des substances chimiques existantes
AICS - Inventaire australien des substances chimiques
KECL - Liste coréenne des substances chimiques existantes et évaluées

15.2 Évaluation de la sécurité chimique

Pas d'information disponible

SECTION 16. Autres informations

Texte intégral des phrases R mentionnées sous les Chapitres 2 et 3
R41 - Risque de lésions oculaires graves
R22 - Nocif en cas d'ingestion
R35 - Provoque de graves brûlures
R10 - Inflammable
R11 - Facilement inflammable
R67 - L'inhalation de vapeurs peut provoquer somnolence et vertiges
R36 - Irritant pour les yeux
R50/53 - Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique
R39/23/24/25 - Toxique: danger d'effets irréversibles très graves par inhalation, par contact avec la peau et par ingestion
R23/24/25 - Toxique par inhalation, par contact avec la peau et par ingestion
R51/53 - Toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique

Texte complet des Phrases-H citées dans les sections 2 et 3
H314 - Provoque des brûlures de la peau et des lésions oculaires graves
H226 - Liquide et vapeurs inflammables
H301 - Toxique en cas d'ingestion
H311 - Toxique par contact cutané
H331 - Toxique par inhalation
H370 - Risque avéré d'effets graves pour les organes (a,b,c) en cas d'inhalation
H225 - Liquide et vapeurs très inflammables
H319 - Provoque une sévère irritation des yeux
H336 - Peut provoquer somnolence ou vertiges
H302 - Nocif en cas d'ingestion
H318 - Provoque des lésions oculaires graves
H400 - Très toxique pour les organismes aquatiques
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
H302 - Nocif en cas d'ingestion
H314 - Provoque des brûlures de la peau et des lésions oculaires graves
H330 - Mortel par inhalation.
H350 - Peut provoquer le cancer
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme

Date d'émission	01-août-2013
Date de révision	01-août-2013
Révision	non applicable.

Cette fiche de données de sécurité est conforme aux exigences du Règlement (CE) No. 1907/2006

Clause de non-responsabilité
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Fin de la Fiche de Données de Sécurité

SAFETY DATA SHEET

Fecha de emisión 01-ago-2013 **Fecha de revisión** 01-ago-2013 **Versión** 1

1. Identificación de la sustancia o la mezcla y de la sociedad o la empresa

1.1 Identificador del producto

Código del producto 901012
Nombre del producto Para-Pak® Zn-PVA Fixative - CS9012
contiene Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

1.2 Usos pertinentes conocidos de la sustancia o de la mezcla y usos desaconsejados

Uso recomendado Fijador

1.3 Datos del proveedor de la ficha de datos de seguridad

Fabricante
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Para informaciones complementarias, por favor ponerse en contacto con:

E-mail de contacto www.meridianbioscience.com

1.4 Teléfono de emergencia

Teléfono de urgencias Teléfono de urgencias CHEMTREC (International) 1-800-424-9300 / 1-703-527-3887 para EE.UU.

2. Identificación de los peligros

2.1 Clasificación de la sustancia o de la mezcla

REGLAMENTO (CE) No 1272/2008

Toxicidad oral aguda	Categoría 4
Toxicidad aguda por inhalación - gas	Categoría 4
Toxicidad aguda por inhalación - polvo/niebla	Categoría 2
Corrosión o irritación cutáneas	Categoría 1 Subcategory 1B
Lesiones o irritación ocular graves	Categoría 1
Carcinogenicidad	Categoría 1A
Toxicidad acuática aguda	Categoría 1
Toxicidad acuática crónica	Categoría 1
Líquidos inflamables	Categoría 2

Clasificación de acuerdo con las Directivas de la UE 67/548/CEE ó 1999/45/CE
El texto completo de las frases R mencionadas en esta Sección, se indica en la Sección 16

Símbolo(s)
Xi - Irritante
F - Fácilmente inflamable
N - Peligroso para el medio ambiente

R-code(s)
F;R11 - Xi;R36 - N;R51/53 - N;R50/53

2.2 Elementos de la etiqueta

Palabra de advertencia
PELIGRO

Indicaciones de peligro
H302 - Nocivo en caso de ingestión
H314 - Provoca quemaduras graves en la piel y lesiones oculares graves
H330 - Mortal en caso de inhalación.
H350 - Puede provocar cáncer
H410 - Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos
H225 - Líquido y vapores muy inflamables
contiene Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

Consejos de prudencia
P304 + P340 - EN CASO DE INHALACIÓN: Transportar a la víctima al exterior y mantenerla en reposo en una posición confortable para respirar
P403 + P233 - Almacenar en un lugar bien ventilado. Mantener el recipiente cerrado herméticamente
P280 - Llevar guantes/ prendas/ gafas/ máscara de protección.
P260 - No respirar los vapores o nieblas
P303 + P361 + P353 - EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitarse inmediatamente las prendas contaminadas. Aclararse la piel con agua o ducharse
P280 - Llevar gafas/ máscara de protección
P305 + P351 + P338 - EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando
P310 - Llamar inmediatamente a un CENTRO DE INFORMACION TOXICOLOGICA o a un médico
P201 - Pedir instrucciones especiales antes del uso
P281 - Utilizar el equipo de protección individual obligatorio
P308 + P313 - EN CASO DE exposición manifiesta o presunta: Consultar a un médico
P370 + P378 - En caso de incendio: Utilizar arena seca, polvo químico seco o espuma resistente al alcohol para apagarlo
P210 - Mantener alejado de fuentes de calor, chispas, llama abierta o superficies calientes. - No fumar.

2.3 Otra información

3. Composición/información sobre los componentes

3.1 Sustancias

3.2 Mezclas

Nombre químico	No. CE	No. CAS	Por ciento en peso	Clasificación (67/548)	Clasificación (Reg. 1272/2008)	Número de registro REACH
Ethyl alcohol	200-578-6	64-17-5	25	F; R11	Flam. Liq. 2 (H225)	sin datos disponibles
Zinc sulfate	231-793-3	7733-02-0	7.9	Xn; R22 Xi; R41 N; R50-53	Acute Tox. 4 (H302) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	sin datos disponibles
Acetic acid	200-580-7	64-19-7	4.8	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	sin datos disponibles
Polyvinyl alcohol	-	9002-89-5	4.6	-	sin datos disponibles	sin datos disponibles
Glycerin	-	56-81-5	1.9	-	sin datos disponibles	sin datos disponibles
Methyl alcohol	Present	67-56-1	1.4	F; R11 T; R23/24/25-39/23/24/25	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	sin datos disponibles
Isopropyl alcohol	200-661-7	67-63-0	1.4	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	sin datos disponibles

El texto completo de las frases R mencionadas en esta Sección, se indica en la Sección 16

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16

4. Primeros auxilios

4.1 Descripción de los primeros auxilios

Contacto con los ojos Enjuagar inmediatamente con abundante agua, también debajo de los párpados, al menos durante 15 minutos. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Requiere atención médica inmediata.

Contacto con la piel Eliminar inmediatamente lavando con jabón y mucha agua desprendiéndose del calzado y de todas las ropas contaminadas. Recabar inmediatamente atención/asesoramiento médico.

Ingestión Llamar inmediatamente a un médico o a un centro de información toxicológica. Requiere atención médica inmediata. Nunca debe administrarse nada por la boca a una persona inconsciente.

Inhalación Sacar al aire libre. Consultar inmediatamente un médico si los síntomas aparecen.

4.2 Principales síntomas y efectos, agudos y retardados

4.3 Indicación de la necesidad de recibir atención médica inmediata y de tratamiento especial

Notas para el médico Tratar sintomáticamente.

5. Medidas de lucha contra incendios

5.1 Medios de extinción

Medios de extinción apropiados
CO_2, dry chemical, dry sand, alcohol-resistant foam.

Medios de extinción que no deben utilizarse por razones de seguridad
No hay información disponible.

5.2 Peligros específicos derivados de la sustancia o la mezcla

Ninguno(a).

5.3 Recomendaciones para el personal de lucha contra incendios

Como en cualquier incendio, utilizar aparatos de respiración autónoma e indumentaria de protección completa.

6. Medidas en caso de vertido accidental

6.1 Precauciones personales, equipo de protección y procedimientos de emergencia

Asegúrese una ventilación apropiada.

Para más información ecológica, ver el apartado 12.

6.2 Precauciones relativas al medio ambiente

No debe liberarse en el medio ambiente. Evite que el producto penetre en el alcantarillado. Impedir nuevos escapes o derrames si puede hacerse sin riesgos.

6.3 Métodos y material de contención y de limpieza

Métodos de limpieza
Absorber con tierra, arena u otro material no combustible y transferir a contenedores para su posterior eliminación.

6.4 Referencia a otras secciones

7. Manipulación y almacenamiento

7.1 Precauciones para una manipulación segura

Consejos para una manipulación segura
No respirar vapores o niebla de pulverización. Asegúrese una ventilación apropiada. Evitar el contacto con la piel, ojos y ropa. Mantener apartado de las llamas abiertas, de las superficies calientes y de los focos de ignición.

7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades

Medidas técnicas/Condiciones de almacenamiento
Mantener los envases herméticamente cerrados en un lugar fresco y bien ventilado. Manténgase separado del calor y de las fuentes de ignición.

7.3 Usos específicos finales

Otras directrices
No hay información disponible.

8. Controles de exposición/protección individual

8.1 Parámetros de control

Límites de exposición Este producto, tal como se suministra, no contiene ningún material peligroso con límites de exposición ocupacional establecidos por los organismos reguladores regionales específicos

Nombre químico	Unión Europea	Reino Unido	Francia	España	Alemania
Ethyl alcohol 64-17-5		STEL: 3000 ppm STEL: 5760 mg/m³ TWA: 1000 ppm TWA: 1920 mg/m³	VME: 1000 ppm VME: 1900 mg/m³ VLCT: 5000 ppm VLCT: 9500 mg/m³	VLA-ED: 1000 ppm VLA-ED: 1910 mg/m³	MAK: 500 ppm MAK: 960 mg/m³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 1920 mg/m³ Skin TWA: 500 ppm TWA: 960 mg/m³
Zinc sulfate 7733-02-0					MAK: 0.1 mg/m³ MAK: 2 mg/m³ Ceiling / Peak: 0.4 mg/m³ Ceiling / Peak: 4 mg/m³
Acetic acid 64-19-7	TWA 10 ppm TWA 25 mg/m³		VLCT: 10 ppm VLCT: 25 mg/m³	VLA-EC: 15 ppm VLA-EC: 37 mg/m³ VLA-ED: 10 ppm VLA-ED: 25 mg/m³	MAK: 10 ppm MAK: 25 mg/m³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³ TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin
Isopropyl alcohol 67-63-0		STEL: 500 ppm STEL: 1250 mg/m³ TWA: 400 ppm TWA: 999 mg/m³	VLCT: 400 ppm VLCT: 980 mg/m³	VLA-EC: 400 ppm VLA-EC: 1000 mg/m³ VLA-ED: 200 ppm VLA-ED: 500 mg/m³	MAK: 200 ppm MAK: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³ TWA: 200 ppm TWA: 500 mg/m³

Component	Italia	Portugal	Países Bajos	Finlandia	Dinamarca
Ethyl alcohol 64-17-5 (25)		TWA: 1000 ppm	Skin STEL: 1900 mg/m³ TWA: 260 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Acetic acid 64-19-7 (4.8)		STEL: 15 ppm TWA: 10 ppm		TWA: 5 ppm TWA: 13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³	TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1 (1.4)	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0 (1.4)		STEL: 400 ppm TWA: 200 ppm		TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³	TWA: 200 ppm TWA: 490 mg/m³

Nombre químico	Austria	Suiza	Polonia	Noruega	Irlanda
Ethyl alcohol 64-17-5	STEL 2000 ppm STEL 3800 mg/m³ MAK: 1000 ppm MAK: 1900 mg/m³	STEL: 1000 ppm STEL: 1920 mg/m³ MAK: 500 ppm MAK: 960 mg/m³	NDS: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Zinc sulfate 7733-02-0		STEL: 0.4 mg/m³ STEL: 4 mg/m³ MAK: 0.1 mg/m³ MAK: 2 mg/m³			
Acetic acid 64-19-7	STEL 20 ppm STEL 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	STEL: 20 ppm STEL: 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	NDSCh: 30 mg/m³ NDS: 15 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 20 ppm STEL: 37.5 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 15 ppm STEL: 37 mg/m³

Methyl alcohol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³ Skin	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0	STEL 800 ppm STEL 2000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	STEL: 400 ppm STEL: 1000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	NDSCh: 1200 mg/m³ NDS: 900 mg/m³ Skin	TWA: 100 ppm TWA: 245 mg/m³ STEL: 150 ppm STEL: 306.25 mg/m³	TWA: 200 ppm STEL: 400 ppm Skin

Nivel sin efecto derivado (DNEL) No hay información disponible

Concentración prevista sin efecto (PNEC) No hay información disponible

8.2 Controles de la exposición

Disposiciones de ingeniería Asegurarse de una ventilación adecuada, especialmente en locales cerrados.

Protección personal

Protección de los ojos Gafas de seguridad ajustadas al contorno del rostro.

Protección de las manos Guantes protectores.

Protección de la piel y del cuerpo Wear impervious rubber clothing if needed to prevent contact with liquid material.

Protección respiratoria Cuando los trabajadores estén expuestos a concentraciones por encima de los límites de exposición, deberán usar mascarillas apropiadas certificadas.

Medidas de higiene Manipular con las precauciones de higiene industrial adecuadas, y respetar las prácticas de seguridad.

Controles de exposición medioambiental Evite que el producto penetre en el alcantarillado.

9. Propiedades físicas y químicas

9.1 Información sobre propiedades físicas y químicas básicas

Estado físico	líquido		
Aspecto	No hay información disponible	**Olor**	No hay información disponible
Color	incoloro	**Umbral olfativo**	No hay información disponible

Propiedades	**Valores**	**Observaciones • Methods**
pH		No hay información disponible
Punto de fusión / punto de congelación		No hay información disponible
Punto /intervalo de ebullición	85 °C / 185 °F	no aplicable
Punto de inflamación	16 °C / 61 °F	no aplicable
Tasa de evaporación		No hay información disponible
Inflamabilidad (sólido, gas)		No hay información disponible
Límites de Inflamabilidad en el Aire		No hay información disponible
límite de inflamabilidad superior		
límite de inflamabilidad inferior		
Presión de vapor		No hay información disponible
Densidad de vapor		No hay información disponible
Gravedad Específicas		No hay información disponible
Solubilidad en agua		Soluble en agua
Solubilidad en otros disolventes		No hay información disponible
Coeficiente de reparto n-octanol/agua		No hay información disponible
Temperatura de auto-inflamación		No hay información disponible
Temperatura de descomposición		No hay información disponible

Viscosidad, cinemática	No hay información disponible
Viscosidad, dinámica	
Propiedades explosivas	No hay información disponible
Propiedades comburentes	No hay información disponible

9.2 Otra información

Temperatura de reblandecimiento	No hay información disponible
Peso molecular	No hay información disponible
Contenido (%) COV (compuestos orgánicos volátiles)	No hay información disponible
Densidad	No hay información disponible
Densidad aparente	No hay información disponible

10. Estabilidad y reactividad

10.1 Reactividad

10.2 Estabilidad química

Estable en condiciones normales.

10.3 Posibilidad de reacciones peligrosas

10.4 Condiciones que deben evitarse

Calor, llamas y chispas.

10.5 Materiales incompatibles

Bases fuertes. Agentes oxidantes.

10.6 Productos de descomposición peligrosos

Ninguno en las condiciones de uso normales.

11. INFORMACIÓN TOXICOLÓGICA

11.1 Información sobre los efectos toxicológicostoxicidad aguda

Toxicidad aguda

Información del Producto	El producto no presenta un riesgo agudo de toxicidad basado en la información conocida o proporcionada.
Inhalación	No existe ningún dato disponible para ese producto.
Contacto con los ojos	No existe ningún dato disponible para ese producto.
Contacto con la piel	No existe ningún dato disponible para ese producto.
Ingestión	No existe ningún dato disponible para ese producto.
Toxicidad aguda	59.5% la mezcla consiste de ingrediente(s) de toxicidad desconocida.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	1,339.00 mg/kg
Cutáneo	4,818.00 mg/kg
Inhalación	
gas	3,344.00 mg/l
Niebla	0.20 mg/l
Vapor	106.70 mg/l

Nombre químico	DL50 Oral	DL50 cutánea	CL50 Inhalación
Ethyl alcohol	7060 mg/kg (Rat)		124.7 mg/L (Rat) 4 h
Zinc sulfate	500 mg/kg (Rat)		
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h
Methyl alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h 64000 ppm (Rat) 4 h
Isopropyl alcohol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Corrosión o irritación cutáneas No hay información disponible.

Daño a los ojos/irritación No hay información disponible.

Sensibilización No hay información disponible.

Mutagenicidad en células germinales No hay información disponible.

Carcinogenicidad No hay información disponible.

Toxicidad para la reproducción No hay información disponible.

Toxicidad específica en determinados órganos - exposición única No hay información disponible.

Toxicidad específica en determinados órganos - exposiciones repetidas No hay información disponible.

Peligro de aspiración No hay información disponible.

12. Información ecológica

12.1 Toxicidad

Efectos ecotoxicológicos Tóxico para los organismos acuáticos, puede provocar a largo plazo efectos negativos en el medio ambiente acuático.

Nombre químico	Toxicidad para las algas	Toxicidad para los peces	Toxicidad para las dafnias y otros invertebrados acuáticos
Ethyl alcohol		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through >100: 96 h Pimephales promelas mg/L LC50 static	10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static 9268 - 14221: 48 h Daphnia magna mg/L LC50

Zinc sulfate	0.056: 72 h Pseudokirchneriella subcapitata mg/L EC50 static 2.4: 96 h Chlorella vulgaris mg/L EC50 64.8: 72 h Chlorella vulgaris mg/L EC50	0.03-0.05: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.06: 96 h Pimephales promelas mg/L LC50 static 0.15: 96 h Cyprinus carpio mg/L LC50 semi-static 0.162: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 0.168-0.25: 96 h Pimephales promelas mg/L LC50 semi-static 0.218-0.42: 96 h Pimephales promelas mg/L LC50 flow-through 0.23-0.48: 96 h Pimephales promelas mg/L LC50 0.34-0.93: 96 h Oncorhynchus mykiss mg/L LC50 static 0.48-1.72: 96 h Poecilia reticulata mg/L LC50 static 0.63: 96 h Poecilia reticulata mg/L LC50 16.85-27.18: 96 h Cyprinus carpio mg/L LC50 static 3-4.6: 96 h Lepomis macrochirus mg/L LC50 flow-through 3.55-6.32: 96 h Lepomis macrochirus mg/L LC50 static 49.23-64.16: 96 h Poecilia reticulata mg/L LC50 semi-static	0.538 - 0.908: 48 h Daphnia magna mg/L EC50 Static 0.75: 48 h Daphnia magna mg/L EC50
Acetic acid		75: 96 h Lepomis macrochirus mg/L LC50 static 79: 96 h Pimephales promelas mg/L LC50 static	47: 24 h Daphnia magna mg/L EC50 65: 48 h Daphnia magna mg/L EC50 Static
Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Isopropyl alcohol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50

12.2 Persistencia y degradabilidad

No hay información disponible.

12.3 Potencial de bioacumulación

No hay información disponible.

Nombre químico	log Pow
Ethyl alcohol	0
Acetic acid	0
Methyl alcohol	-0.77
Isopropyl alcohol	0.05

12.4 Movilidad en el suelo

Movilidad
No hay información disponible.

12.5 Resultados de la valoración PBT y MPMB

No hay información disponible.

12.6 Otros efectos adversos.

13. Consideraciones relativas a la eliminación

13.1 Métodos para el tratamiento de residuos

Desechos de residuos / producto no utilizado Disponer como desechos peligrosos de acuerdo con las regulaciones locales y nacionales. No debe liberarse en el medio ambiente.

Envases contaminados Eliminar, observando las normas locales en vigor. No reutilizar los recipientes vacíos.

14. Información relativa al transporte

ICAO/IATA	Flammable Liquid, Corrosive, n.o.s.
14.1. No. UN/ID	2924
14.2. Designación oficial de transporte de las Naciones Unidas	Ethanol, Acetic Acid
14.3. Clase de peligro	3
Clase subsidiaria de peligro	8
14.4. Grupo de embalaje	II
Descripción	Para-Pak® Zn-PVA
14.5. Provisiones Especiales	ninguno(a)
14.6. Nota	Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

15. Información reglamentaria

15.1 Reglamentación y legislación en materia de seguridad, salud y medio ambiente específicas para la sustancia o la mezcla

Nombre químico	French RG number
Ethyl alcohol	RG 84
Methyl alcohol	RG 84
Isopropyl alcohol	RG 84

Inventarios Internacionales

TSCA	Cumple
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
China	-
AICS	-
KECL	-

Leyenda
TSCA : Ley de Control de Sustancias Tóxicas estadounidense, apartado 8(b), Inventario
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL : Lista de Sustancias Domésticas Canadiense/Lista de Sustancias No Domésticas Canadiense
PICCS - Inventario filipino de sustancias y preparados químicos
ENCS - Inventario japonés de sustancias químicas existentes y nuevas
IECSC - Inventario chino de sustancias químicas existentes
AICS - Inventario australiano de sustancias químicas
KECL - Inventario coreano de sustancias químicas existentes y evaluadas

15.2 Evaluación de la seguridad química

No hay información disponible

16. Otra información

El texto completo de las frases-R referidas en los puntos 2 y 3
R41 - Riesgo de lesiones oculares graves
R22 - Nocivo por ingestión
R35 - Provoca quemaduras graves
R10 - Inflamable
R11 - Fácilmente inflamable
R67 - La inhalación de vapores puede provocar somnolencia y vértigo
R36 - Irrita los ojos
R50/53 - Muy tóxico para los organismos acuáticos, puede provocar a largo plazo efectos negativos en el medio ambiente acuático
R39/23/24/25 - Tóxico: peligro de efectos irreversibles muy graves por inhalación, contacto con la piel e ingestión
R23/24/25 - Tóxico por inhalación, por ingestión y en contacto con la piel
R51/53 - Tóxico para los organismos acuáticos, puede provocar a largo plazo efectos negativos en el medio ambiente acuático

Texto íntegro de las Declaraciones-H referidas en las secciones 2 y 3
H314 - Provoca quemaduras graves en la piel y lesiones oculares graves
H226 - Líquidos y vapores inflamables
H301 - Tóxico en caso de ingestión
H311 - Tóxico en contacto con la piel
H331 - Tóxico en caso de inhalación
H370 - Provoca daños en los órganos (a,b,c) si se inhala
H225 - Líquido y vapores muy inflamables
H319 - Provoca irritación ocular grave
H336 - Puede provocar somnolencia o vértigo
H302 - Nocivo en caso de ingestión
H318 - Provoca lesiones oculares graves
H400 - Muy tóxico para los organismos acuáticos
H410 - Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos
H302 - Nocivo en caso de ingestión
H314 - Provoca quemaduras graves en la piel y lesiones oculares graves
H330 - Mortal en caso de inhalación.
H350 - Puede provocar cáncer
H410 - Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos

Fecha de emisión	01-ago-2013
Fecha de revisión	01-ago-2013
Nota de revisión	no aplicable.

La hoja técnica de seguridad cumple con los requisitos de la Reglamento (CE) No. 1907/2006

De responsabilidad
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Fin de la Ficha de Datos de Seguridad

SAFETY DATA SHEET

Ausgabedatum 01-Aug-2013 **Überarbeitet am** 01-Aug-2013 **Version** 1

1. Bezeichnung des Stoffs bzw. des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktnummer 901012
Produktname Para-Pak® Zn-PVA Fixative - CS9012
Enthält Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

1.2 Relevante ermittelte Verwendungszwecke des Stoffs oder Gemischs und Verwendungszwecke, von denen abgeraten wird

Empfohlener Anwendungsbereich Fixiermittel

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Für weitere Informationen bitte kontaktieren:

Email-Adresse www.meridianbioscience.com

1.4 Notfall-Telefonnummer

Notrufnummer Notrufnummer CHEMTREC (International) 1-800-424-9300 / für USA 1-703-527-3887

2. Mögliche Gefahren

2.1 Einstufung des Stoffs oder Gemischs

VERORDNUNG (EG) Nr. 1272/2008

Akuter oraler Toxizität	Kategorie 4
Akute Toxizität bei Inhalation - gas	Kategorie 4
Akute Toxizität bei Inhalation - Staub/Nebel	Kategorie 2
Ätz-/Reizwirkung auf die Haut	Kategorie 1 Subcategory 1B
Schwere Augenschädigung/-reizung	Kategorie 1
Karzinogenität	Kategorie 1A
Akute aquatische Toxizität	Kategorie 1
Chronische aquatische Toxizität	Kategorie 1
Entzündbare Flüssigkeiten	Kategorie 2

Einstufung gemäss EU-Richtlinien 67/548/EWG oder 1999/45/EG
Den vollen Wortlaut der hier genannten R-Sätze finden Sie in Abschnitt 16

Symbol(e)
Xi - Reizend
F - Leichtentzündlich
N - Umweltgefährlich

R-code(s)
F;R11 - Xi;R36 - N;R51/53 - N;R50/53

2.2 Kennzeichnungselemente

Signalwort
GEFAHR

Gefahrenhinweise
H302 - Gesundheitsschädlich bei Verschlucken
H314 - Verursacht schwere Verätzungen der Haut und schwere Augenschäden
H330 - Lebensgefahr bei Einatmen.
H350 - Kann Krebs erzeugen
H410 - Sehr giftig für Wasserorganismen mit langfristiger Wirkung
H225 - Flüssigkeit und Dampf leicht entzündbar
Enthält Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

Sicherheitshinweise
P304 + P340 - BEI EINATMEN: An die frische Luft bringen und in einer Position ruhigstellen, die das Atmen erleichtert
P403 + P233 - Behälter dicht verschlossen an einem gut belüfteten Ort aufbewahren.
P280 - Schutzhandschuhe/ Schutzkleidung/ Augenschutz/ Gesichtsschutz tragen.
P260 - Staub oder Nebel nicht einatmen
P303 + P361 + P353 - BEI KONTAKT MIT DER HAUT (oder dem Haar): Alle beschmutzten, getränkten Kleidungsstücke sofort ausziehen. Haut mit Wasser abwaschen/ duschen.
P280 - Augenschutz/ Gesichtsschutz tragen
P305 + P351 + P338 - BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
P310 - Sofort GIFTINFORMATIONSZENTRUM oder Arzt anrufen
P201 - Vor Gebrauch besondere Anweisungen einholen
P281 - Vorgeschriebene persönliche Schutzausrüstung verwenden
P308 + P313 - BEI Exposition oder falls betroffen: Ärztlichen Rat einholen/ ärztliche Hilfe hinzuziehen.
P370 + P378 - Bei Brand: Zum Löschen Trockensand, Trockenlöschmittel oder alkoholbeständigen Schaum verwenden
P210 - Von Hitze/Funken/offener Flamme/heißen Oberflächen fernhalten. Nicht rauchen.

2.3 Sonstige Angaben

3. Zusammensetzung/Angaben zu Bestandteilen

3.1 Stoffe

3.2 Gemische

Chemische Bezeichnung	EG-Nr	CAS-Nr	Gewichtsprozent	Einstufung (67/548)	Einstufung (VO (EG) 1272/2008)	REACH Registrierungsnummer
Ethyl alcohol	200-578-6	64-17-5	25	F; R11	Flam. Liq. 2 (H225)	Keine Daten verfügbar
Zinc sulfate	231-793-3	7733-02-0	7.9	Xn; R22 Xi; R41 N; R50-53	Acute Tox. 4 (H302) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Keine Daten verfügbar
Acetic acid	200-580-7	64-19-7	4.8	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	Keine Daten verfügbar
Polyvinyl alcohol	-	9002-89-5	4.6	-	Keine Daten verfügbar	Keine Daten verfügbar
Glycerin	-	56-81-5	1.9	-	Keine Daten verfügbar	Keine Daten verfügbar
Methyl alcohol	Present	67-56-1	1.4	F; R11 T; R23/24/25-39/23/24/25	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	Keine Daten verfügbar
Isopropyl alcohol	200-661-7	67-63-0	1.4	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	Keine Daten verfügbar

Den vollen Wortlaut der hier genannten R-Sätze finden Sie in Abschnitt 16

Den Volltext der in diesem Abschnitt aufgeführten Gefahrenhinweise finden sie unter Abschnitt 16

4. Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Augenkontakt Sofort mit viel Wasser mindestens 15 Minuten lang ausspülen, auch unter den Augenlidern. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Eine sofortige ärztliche Betreuung ist notwendig.

Hautkontakt Sofort mit Seife und viel Wasser abwaschen. Beschmutzte Kleidung und Schuhe ausziehen. Sofort ärztlichen Behandlung/Rat aufsuchen.

Verschlucken Sofort einen Arzt oder ein Behandlungszentrum für Vergiftungsfälle verständigen. Eine sofortige ärztliche Betreuung ist notwendig. Nie einer ohnmächtigen Person etwas durch den Mund einflößen.

Einatmen An die frische Luft bringen. Bei Auftreten von Symptomen, sofort ärztliche Betreuung aufsuchen.

4.2 Wichtigste sowohl akute als auch verzögerte Symptome und Auswirkungen

4.3 Angabe der benötigten ärztlichen Soforthilfe und Spezialbehandlung

Hinweise für den Arzt Symptomatische Behandlung.

5. Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel
CO_2, dry chemical, dry sand, alcohol-resistant foam.

Löschmittel, die aus Sicherheitsgründen nicht zu verwenden sind
Keine Information verfügbar.

5.2 Besondere von dem betreffenden Stoff oder Gemisch ausgehende Gefahren

kein(e,er).

5.3 Hinweise für die Brandbekämpfung

Wie bei jedem Feuer schweres Atemschutzgerät und volle Schutzausrüstung tragen.

6. Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Für angemessene Lüftung sorgen.

Weitere Angaben zur Ökologie im Abschnitt 12.

6.2 Umweltschutzmaßnahmen

Nicht in die Umwelt gelangen lassen. Vorsorge treffen, dass das Produkt nicht in die Kanalisation gelangt. Weiteres Auslaufen oder Verschütten verhindern, wenn dies ohne Gefahr möglich ist.

6.3 Methoden und Material für Eindämmung und Reinigung

Reinigungsverfahren
Mit Erde, Sand oder anderen nicht brennbaren Materialien aufsaugen und zur späteren Entsorgung in Behälter füllen.

6.4 Verweis auf andere Abschnitte

7. Handhabung und Lagerung

7.1 Vorsichtsmaßnahmen für eine sichere Handhabung

Hinweise zum sicheren Umgang
Dämpfe und Sprühnebel nicht einatmen. Für angemessene Lüftung sorgen. Kontakt mit Haut, Augen und Kleidung vermeiden. Von offenen Flammen, heißen Oberflächen und Zündquellen fernhalten.

7.2 Bedingungen für eine sichere Lagerung unter Berücksichtigung von Unverträglichkeiten

Technische Maßnahmen/Lagerungsbedingungen
Behälter dicht verschlossen an einem kühlen, gut belüfteten Ort aufbewahren. Von Hitze- und Zündquellen fernhalten.

7.3 Spezifische Endverwendungszwecke

Andere Richtlinien
Keine Information verfügbar.

8. Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstungen

8.1 Zu überwachende Parameter

Expositionsgrenzwerte Das Produkt enthält in der gelieferten Form keine Gefahrstoffe mit von den für die Region zuständigen Bestimmungsbehörden festgelegten Expositionsgrenzen am Arbeitsplatz

Chemische Bezeichnung	Europäische Union	Großbritannien	Frankreich	Spanien	Deutschland
Ethyl alcohol 64-17-5		STEL: 3000 ppm STEL: 5760 mg/m³ TWA: 1000 ppm TWA: 1920 mg/m³	VME: 1000 ppm VME: 1900 mg/m³ VLCT: 5000 ppm VLCT: 9500 mg/m³	VLA-ED: 1000 ppm VLA-ED: 1910 mg/m³	MAK: 500 ppm MAK: 960 mg/m³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 1920 mg/m³ Skin TWA: 500 ppm TWA: 960 mg/m³
Zinc sulfate 7733-02-0					MAK: 0.1 mg/m³ MAK: 2 mg/m³ Ceiling / Peak: 0.4 mg/m³ Ceiling / Peak: 4 mg/m³
Acetic acid 64-19-7	TWA 10 ppm TWA 25 mg/m³		VLCT: 10 ppm VLCT: 25 mg/m³	VLA-EC: 15 ppm VLA-EC: 37 mg/m³ VLA-ED: 10 ppm VLA-ED: 25 mg/m³	MAK: 10 ppm MAK: 25 mg/m³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³ TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin
Isopropyl alcohol 67-63-0		STEL: 500 ppm STEL: 1250 mg/m³ TWA: 400 ppm TWA: 999 mg/m³	VLCT: 400 ppm VLCT: 980 mg/m³	VLA-EC: 400 ppm VLA-EC: 1000 mg/m³ VLA-ED: 200 ppm VLA-ED: 500 mg/m³	MAK: 200 ppm MAK: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³ TWA: 200 ppm TWA: 500 mg/m³

Component	Italien	Portugal	Die Niederlande	Finnland	Dänemark
Ethyl alcohol 64-17-5 (25)		TWA: 1000 ppm	Skin STEL: 1900 mg/m³ TWA: 260 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Acetic acid 64-19-7 (4.8)		STEL: 15 ppm TWA: 10 ppm		TWA: 5 ppm TWA: 13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³	TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1 (1.4)	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0 (1.4)		STEL: 400 ppm TWA: 200 ppm		TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³	TWA: 200 ppm TWA: 490 mg/m³

Chemische Bezeichnung	Österreich	Schweiz	Polen	Norwegen	Irland
Ethyl alcohol 64-17-5	STEL 2000 ppm STEL 3800 mg/m³ MAK: 1000 ppm MAK: 1900 mg/m³	STEL: 1000 ppm STEL: 1920 mg/m³ MAK: 500 ppm MAK: 960 mg/m³	NDS: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Zinc sulfate 7733-02-0		STEL: 0.4 mg/m³ STEL: 4 mg/m³ MAK: 0.1 mg/m³ MAK: 2 mg/m³			
Acetic acid 64-19-7	STEL 20 ppm STEL 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	STEL: 20 ppm STEL: 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	NDSCh: 30 mg/m³ NDS: 15 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 20 ppm STEL: 37.5 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 15 ppm STEL: 37 mg/m³

Methyl alcohol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³ Skin	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0	STEL 800 ppm STEL 2000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	STEL: 400 ppm STEL: 1000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	NDSCh: 1200 mg/m³ NDS: 900 mg/m³ Skin	TWA: 100 ppm TWA: 245 mg/m³ STEL: 150 ppm STEL: 306.25 mg/m³	TWA: 200 ppm STEL: 400 ppm Skin

Abgeleitete Expositionshöhe ohne Beeinträchtigung (DNEL) Keine Information verfügbar

Abgeschätzte Nicht-Effekt-Konzentration (PNEC) Keine Information verfügbar

8.2 Begrenzung und Überwachung der Exposition

Technische Schutzmaßnahmen Für ausreichende Belüftung sorgen, besonders in geschlossenen Räumen.

Persönliche Schutzausrüstung

Augenschutz Dicht schließende Schutzbrille.

Handschutz Schutzhandschuhe.

Haut- und Körperschutz Wear impervious rubber clothing if needed to prevent contact with liquid material.

Atemschutz Bei Konzentrationen über den AGW-Werten ist ein entsprechendes, geprüftes Atemschutzgerät zu tragen.

Hygienemaßnahmen Die beim Umgang mit Chemikalien üblichen Vorsichtsmaßnahmen sind zu beachten.

Begrenzung und Überwachung der Umweltexposition Vorsorge treffen, dass das Produkt nicht in die Kanalisation gelangt.

9. Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Aggregatzustand	Flüssigkeit		
Aussehen	Keine Information verfügbar	**Geruch**	Keine Information verfügbar
Farbe	farblos	**Geruchsschwelle**	Keine Information verfügbar

Eigenschaft	**Werte**	**Bemerkungen • Methods**
pH-Wert		Keine Information verfügbar
Schmelzpunkt/Gefrierpunkt		Keine Information verfügbar
Siedepunkt/Siedebereich	85 °C / 185 °F	nicht anwendbar
Flammpunkt	16 °C / 61 °F	nicht anwendbar
Verdampfungsgeschwindigkeit		Keine Information verfügbar
Entzündbarkeit (fest, gasförmig)		Keine Information verfügbar
Entzündlichkeitsgrenzwert in der Luft		Keine Information verfügbar
obere Zündgrenze		
untere Zündgrenze		
Dampfdruck		Keine Information verfügbar
Dampfdichte		Keine Information verfügbar
Spezifisches Gewicht		Keine Information verfügbar
Wasserlöslichkeit		Löslich in Wasser
Löslichkeit in anderen Lösungsmitteln		Keine Information verfügbar
Verteilungskoeffizient: n-Octanol/Wasser		Keine Information verfügbar
Selbstentzündungstemperatur		Keine Information verfügbar
Zersetzungstemperatur		Keine Information verfügbar

Viskosität, kinematisch	Keine Information verfügbar
Viskosität, dynamisch	
Explosionsgefahr	Keine Information verfügbar
Oxidierende Eigenschaften	Keine Information verfügbar

9.2 Sonstige Angaben

Erweichungspunkt	Keine Information verfügbar
Molekulargewicht	Keine Information verfügbar
Gehalt (%)der flüchtigen organischen Verbindung	Keine Information verfügbar
Dichte	Keine Information verfügbar
Schüttdichte	Keine Information verfügbar

10. Stabilität und Reaktivität

10.1 Reaktivität

10.2 Chemische Stabilität

Stabil unter normalen Bedingungen.

10.3 Möglichkeit gefährlicher Reaktionen

10.4 Zu vermeidende Bedingungen

Hitze, Flammen und Funken.

10.5 Unverträgliche Materialien

Starke Basen. Oxidationsmittel.

10.6 Gefährliche Zersetzungsprodukte

Bei normalen Verwendungsbedingungen keine.

11. Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

Akute Toxizität

Produktinformation	Das Produkt stellt gemäß bekannter oder verfügbarer Informationen keine akute Vergiftungsgefahr dar.
Einatmen	Für dieses Produkt sind keine Daten verfügbar.
Augenkontakt	Für dieses Produkt sind keine Daten verfügbar.
Hautkontakt	Für dieses Produkt sind keine Daten verfügbar.
Verschlucken	Für dieses Produkt sind keine Daten verfügbar.
Akute Toxizität	59.5% der Mischung besteht aus einem Bestandteil/Bestandteilen mit unbekannter Toxizität.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	1,339.00 mg/kg
Haut	4,818.00 mg/kg
Einatmen	
Gas	3,344.00 mg/l
Nebel	0.20 mg/l

Dampf 106.70 mg/l

Chemische Bezeichnung	LD50 Oral	LD50 Dermal	LC50 Einatmen
Ethyl alcohol	7060 mg/kg (Rat)		124.7 mg/L (Rat) 4 h
Zinc sulfate	500 mg/kg (Rat)		
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h
Methyl alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h 64000 ppm (Rat) 4 h
Isopropyl alcohol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Ätz-/Reizwirkung auf die Haut Keine Information verfügbar.

Augenschaden/-reizung Keine Information verfügbar.

Sensibilisierung Keine Information verfügbar.

Keimzell-Mutagenität Keine Information verfügbar.

Karzinogenität Keine Information verfügbar.

Reproduktionstoxizität Keine Information verfügbar.

Spezifische Zielorgan-Toxizität - einmalige Exposition Keine Information verfügbar.

Spezifische Zielorgan-Toxizität - wiederholte Exposition Keine Information verfügbar.

Aspirationsgefahr Keine Information verfügbar.

12. Umweltbezogene Angaben

12.1 Toxizität

Ökotoxische Wirkungen Giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben.

Chemische Bezeichnung	Toxizität gegenüber Algen	Toxizität gegenüber Fischen	Toxizität gegenüber Daphnien und anderen wirbellosen Wassertieren
Ethyl alcohol		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through >100: 96 h Pimephales promelas mg/L LC50 static	10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static 9268 - 14221: 48 h Daphnia magna mg/L LC50

Zinc sulfate	0.056: 72 h Pseudokirchneriella subcapitata mg/L EC50 static 2.4: 96 h Chlorella vulgaris mg/L EC50 64.8: 72 h Chlorella vulgaris mg/L EC50	0.03-0.05: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.06: 96 h Pimephales promelas mg/L LC50 static 0.15: 96 h Cyprinus carpio mg/L LC50 semi-static 0.162: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 0.168-0.25: 96 h Pimephales promelas mg/L LC50 semi-static 0.218-0.42: 96 h Pimephales promelas mg/L LC50 flow-through 0.23-0.48: 96 h Pimephales promelas mg/L LC50 0.34-0.93: 96 h Oncorhynchus mykiss mg/L LC50 static 0.48-1.72: 96 h Poecilia reticulata mg/L LC50 static 0.63: 96 h Poecilia reticulata mg/L LC50 16.85-27.18: 96 h Cyprinus carpio mg/L LC50 static 3-4.6: 96 h Lepomis macrochirus mg/L LC50 flow-through 3.55-6.32: 96 h Lepomis macrochirus mg/L LC50 static 49.23-64.16: 96 h Poecilia reticulata mg/L LC50 semi-static	0.538 - 0.908: 48 h Daphnia magna mg/L EC50 Static 0.75: 48 h Daphnia magna mg/L EC50
Acetic acid		75: 96 h Lepomis macrochirus mg/L LC50 static 79: 96 h Pimephales promelas mg/L LC50 static	47: 24 h Daphnia magna mg/L EC50 65: 48 h Daphnia magna mg/L EC50 Static
Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Isopropyl alcohol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50

12.2 Persistenz und Abbaubarkeit

Keine Information verfügbar.

12.3 Bioakkumulationspotenzial

Keine Information verfügbar.

Chemische Bezeichnung	log Pow
Ethyl alcohol	0
Acetic acid	0
Methyl alcohol	-0.77
Isopropyl alcohol	0.05

12.4 Mobilität im Boden

Mobilität
Keine Information verfügbar.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Keine Information verfügbar.

12.6 Andere schädliche Wirkungen.

13. Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Abfälle von Restmengen / ungebrauchten Produkten	Unter Beachtung der örtlichen und nationalen gesetzlichen Vorschriften als gefährlicher Abfall entsorgen. Nicht in die Umwelt gelangen lassen.
Verunreinigte Verpackungen	Unter Beachtung der örtlichen behördlichen Bestimmungen beseitigen. Leere Behälter nicht wieder verwenden.

14. Angaben zum Transport

ICAO/IATA	Flammable Liquid, Corrosive, n.o.s.
14.1. UN/ID-Nr	2924
14.2. Ordnungsgemäße UN-Versandbezeichnung	Ethanol, Acetic Acid
14.3. Gefahrklasse	3
Untergeordnete Gefahrklasse	8
14.4. Verpackungsgruppe	II
Beschreibung	Para-Pak® Zn-PVA
14.5. Sondervorschriften	Kein(e,er)
14.6. Bemerkung	Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

15. Rechtsvorschriften

15.1 Vorschriften zu Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

Chemische Bezeichnung	French RG number
Ethyl alcohol	RG 84
Methyl alcohol	RG 84
Isopropyl alcohol	RG 84

Internationale Bestandsverzeichnisse

TSCA	Erfüllt
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
China	-
AICS	-
KECL	-

Legende
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory - Verzeichnis nach §8(b) des Gesetzes zur Minderung toxischer Stoffe (TSCA) der USA
EINECS/ELINCS - Europäisches Verzeichnis existierender kommerzieller chemischer Substanzen/Eu Liste der angemeldeten chemischen Stoffe
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List - Kanadisches Chemikalienverzeichis Inland/Ausland
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances - Japanisches Verzeichnis chemischer Alt- und Neustoffe
IECSC - China Inventory of Existing Chemical Substances
AICS – Australischer Warenbestand der chemischen Substanzen
KECL - Korean Existing and Evaluated Chemical Substances - Südkoreanisches Chemikalienverzeichnis

15.2 Stoffsicherheitsbeurteilung

Keine Information verfügbar

16. Sonstige Angaben

Vollständiger Wortlaut der in den Kapiteln 2 und 3 aufgeführten R-Sätze
R41 - Gefahr ernster Augenschäden
R22 - Gesundheitsschädlich beim Verschlucken
R35 - Verursacht schwere Verätzungen
R10 - Entzündlich
R11 - Leichtentzündlich
R67 - Dämpfe können Schläfrigkeit und Benommenheit verursachen
R36 - Reizt die Augen
R50/53 - Sehr giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben
R39/23/24/25 - Giftig: ernste Gefahr irreversiblen Schadens durch Einatmen, Berührung mit der Haut und durch Verschlucken
R23/24/25 - Giftig beim Einatmen, Verschlucken und Berührung mit der Haut
R51/53 - Giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben

Volltext der Gefahrenhinweise in Abschnitt 2 und 3
H314 - Verursacht schwere Verätzungen der Haut und schwere Augenschäden
H226 - Flüssigkeit und Dampf entzündbar
H301 - Giftig bei Verschlucken
H311 - Giftig bei Hautkontakt
H331 - Giftig bei Einatmen
H370 - Schädigt die Organe (a,b,c) bei Einatmen
H225 - Flüssigkeit und Dampf leicht entzündbar
H319 - Verursacht schwere Augenreizung
H336 - Kann Schläfrigkeit und Benommenheit verursachen
H302 - Gesundheitsschädlich bei Verschlucken
H318 - Verursacht schwere Augenschäden
H400 - Sehr giftig für Wasserorganismen
H410 - Sehr giftig für Wasserorganismen mit langfristiger Wirkung
H302 - Gesundheitsschädlich bei Verschlucken
H314 - Verursacht schwere Verätzungen der Haut und schwere Augenschäden
H330 - Lebensgefahr bei Einatmen.
H350 - Kann Krebs erzeugen
H410 - Sehr giftig für Wasserorganismen mit langfristiger Wirkung

Ausgabedatum	01-Aug-2013
Überarbeitet am	01-Aug-2013
Abänderungsvermerk	nicht anwendbar.

Dieses Sicherheitsdatenblatt erfüllt die Anforderungen der Verordnung (EG) Nr. 1907/2006

Haftungsausschluss
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Ende des Sicherheitsdatenblatts

VEILIGHEIDSINFORMATIEBLAD.

Datum van uitgifte 01-aug-2013 **Herzieningsdatum** 01-aug-2013 **Versie** 1

Identificatie van de stof of het mengsel en van de vennootschap/onderneming

1.1 Productidentificatie

Productcode 901012
Productbenaming Para-Pak® Zn-PVA Fixative - CS9012
bevat Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

1.2 Relevant geïdentificeerd gebruik van de stof of het mengsel en ontraden gebruik

Aanbevolen gebruik Fixative

1.3 Details betreffende de verstrekker van het veiligheidsinformatieblad

Fabrikant
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Authorized Representative
Meridian Bioscience Europe
Via del' Industria 7
20020 Villa Cortese Milano, Italy

Voor verdere informatie contact opnemen met:

E-mailadres www.meridianbioscience.com

1.4 Telefoonnummer voor noodgevallen

Telefoonnummer voor noodgevallen Telefoonnummer voor noodgevallen CHEMTREC (International) 1-800-424-9300 / Voor de Verenigde Staten 1-703-527-3887

2. Identificatie van de gevaren

2.1 Indeling van de stof of het mengsel

VERORDENING (EG) Nr. 1272/2008

Acute orale toxiciteit	Categorie 4
Acute inhalatoire toxiciteit - gas	Categorie 4
Acute inhalatoire toxiciteit - stof/nevel	Categorie 2
Huidcorrosie/-irritatie	Categorie 1 Subcategory 1B
Ernstig oogletsel/oogirritatie	Categorie 1
Kankerverwekkendheid	Categorie 1A
Acute aquatische toxiciteit	Categorie 1
Chronische aquatische toxiciteit	Categorie 1
Ontvlambare vloeistoffen	Categorie 2

Classificatie volgens EU-Richtlijnen 67/548/EEG of 1999/45/EG
Voor de volledige tekst van de R-zinnen die worden genoemd in deze paragraaf, zie Paragraaf 16

Symbo(o)l(en)
Xi - Irriterend
F - Licht ontvlambaar
N - Milieugevaarlijk

R-code(s)
F;R11 - Xi;R36 - N;R51/53 - N;R50/53

2.2 Etiketteringselementen

Signaalwoord
GEVAAR

Gevarenaanduidingen
H302 - Schadelijk bij inslikken
H314 - Veroorzaakt ernstige brandwonden en oogletsel
H330 - Dodelijk bij inademing.
H350 - Kan kanker veroorzaken
H410 - Zeer giftig voor in het water levende organismen, met langdurige gevolgen
H225 - Licht ontvlambare vloeistof en damp
bevat Zinc sulfate, Methyl alcohol, Isopropyl alcohol, Ethyl alcohol

Veiligheidsaanbevelingen
P304 + P340 - NA INADEMING: het slachtoffer in de frisse lucht brengen en laten rusten in een houding die het ademen vergemakkelijkt
P403 + P233 - Op een goed geventileerde plaats bewaren. In goed gesloten verpakking bewaren.
P280 - Beschermende handschoenen/ beschermende kleding/ oogbescherming/ gelaatsbescherming dragen.
P260 - Voorkom inademen van stof of nevel
P303 + P361 + P353 - BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken - huid met water afspoelen/ afdouchen.
P280 - Oogbescherming/ gelaatsbescherming dragen
P305 + P351 + P338 - BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen.
P310 - Onmiddellijk een ANTIGIFCENTRUM of een arts raadplegen
P201 - Alvorens te gebruiken de speciale aanwijzingen raadplegen
P281 - De nodige persoonlijke beschermingsuitrusting gebruiken
P308 + P313 - NA (mogelijke) blootstelling: een arts raadplegen
P370 + P378 - In geval van brand: Gebruik droog zand, droge chemicaliën of alcoholbestendige schuim voor uitdoven
P210 - Verwijderd houden van warmte/vonken/open vuur/hete oppervlakken. - Niet roken.

2.3 Overige informatie

3. Samenstelling en informatie over de bestanddelen

3.1 Stoffen

3.2 Mengsels

Chemische naam	EG-Nr	CAS-Nr	Massaprocent	Indeling (67/548)	GHS Classificatie	REACH registratienummer
Ethyl alcohol	200-578-6	64-17-5	25	F; R11	Flam. Liq. 2 (H225)	geen gegevens beschikbaar
Zinc sulfate	231-793-3	7733-02-0	7.9	Xn; R22 Xi; R41 N; R50-53	Acute Tox. 4 (H302) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	geen gegevens beschikbaar
Acetic acid	200-580-7	64-19-7	4.8	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	geen gegevens beschikbaar
Polyvinyl alcohol	-	9002-89-5	4.6	-	geen gegevens beschikbaar	geen gegevens beschikbaar
Glycerin	-	56-81-5	1.9	-	geen gegevens beschikbaar	geen gegevens beschikbaar
Methyl alcohol	Present	67-56-1	1.4	F; R11 T; R23/24/25-39/23/24/25	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	geen gegevens beschikbaar
Isopropyl alcohol	200-661-7	67-63-0	1.4	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	geen gegevens beschikbaar

Voor de volledige tekst van de R-zinnen die worden genoemd in deze paragraaf, zie Paragraaf 16

Voor de volledige text van H-zinnen zoals vermeld in deze paragraaf, zie paragraaf 16

4. Eerstehulpmaatregelen

4.1 Beschrijving van de eerstehulpmaatregelen

Aanraking met de ogen Onmiddellijk spoelen met veel water, ook onder de oogleden, gedurende tenminste 15 minuten. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Onmiddellijke medische zorg is noodzakelijk.

Aanraking met de huid Onmiddellijk afwassen met zeep en veel water en alle verontreinigde kleding en schoenen uittrekken. Zoek onmiddellijk medische hulp/advies.

Inslikken Onmiddellijk een arts of gifinformatiecentrum waarschuwen. Onmiddellijke medische zorg is noodzakelijk. Nooit een bewusteloos persoon laten drinken (of eten).

Inademing In de frisse lucht brengen. Meteen medische hulp inroepen als symptomen optreden.

4.2 Belangrijkste acute en uitgestelde symptomen en effecten

4.3 Indicatie van onmiddelijke medische hulp en vereiste speciale behandeling

Opmerkingen voor de arts Symptomatisch behandelen.

5. Brandbestrijdingsmaatregelen

5.1 Blusmiddelen

Geschikte blusmiddelen
CO_2, dry chemical, dry sand, alcohol-resistant foam.

Blusmiddelen die om veiligheidsredenen niet gebruikt mogen worden
Geen gegevens beschikbaar.

5.2 Speciale gevaren die door de stof of het mengsel worden veroorzaakt

Geen.

5.3 Advies voor brandweerlieden

Draag, net als bij elke andere brand, onafhankelijke ademhalingsapparatuur en een volledig beschermende uitrusting.

6. Maatregelen bij het accidenteel vrijkomen van de stof of het mengsel

6.1 Persoonlijke voorzorgsmaatregelen, beschermde uitrusting en noodprocedures

Zorg voor voldoende ventilatie.

Zie sectie 12 voor aanvullende ecologische informatie.

6.2 Milieuvoorzorgsmaatregelen

Mag niet in het milieu vrijkomen. Voorkom dat product in riolering komt. Voorkom verder lekken en morsen indien dit veilig is.

6.3 Insluitings- en reinigingsmethoden en -materiaal

Reinigingsmethoden
Absorberen met aarde, zand of een ander niet-ontvlambaar materiaal en overbrengen naar vaten voor latere verwijdering.

6.4 Verwijzing naar andere rubrieken

7. Hantering en opslag

7.1 Voorzorgsmaatregelen voor het veilig hanteren van de stof of het mengsel

Advies voor veilige hantering
Dampen of spuitnevel niet inademen. Zorg voor voldoende ventilatie. Aanraking met ogen, huid en kleding vermijden. Verwijderd houden van open vuur, hete oppervlakken en ontstekingsbronnen.

7.2 Voorwaarden voor een veilige opslag, met inbegrip van incompatibele producten

Technische maatregelen/Opslagomstandigheden
Containers goed afgesloten bewaren op een koele en goed geventileerde plaats. Verwijderd houden van warmte en ontstekingsbronnen.

7.3 Specifiek eindgebruik

Overige richtlijnen
Geen gegevens beschikbaar.

8. Maatregelen ter beheersing van blootstelling/persoonlijke bescherming

8.1 Controleparameters

Blootstellingslimieten This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemische naam	Europese Unie	Het Verenigd Koninkrijk	Frankrijk	Spanje	Duitsland
Ethyl alcohol 64-17-5		STEL: 3000 ppm STEL: 5760 mg/m³ TWA: 1000 ppm TWA: 1920 mg/m³	VME: 1000 ppm VME: 1900 mg/m³ VLCT: 5000 ppm VLCT: 9500 mg/m³	VLA-ED: 1000 ppm VLA-ED: 1910 mg/m³	MAK: 500 ppm MAK: 960 mg/m³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 1920 mg/m³ Skin TWA: 500 ppm TWA: 960 mg/m³
Zinc sulfate 7733-02-0					MAK: 0.1 mg/m³ MAK: 2 mg/m³ Ceiling / Peak: 0.4 mg/m³ Ceiling / Peak: 4 mg/m³
Acetic acid 64-19-7	TWA 10 ppm TWA 25 mg/m³		VLCT: 10 ppm VLCT: 25 mg/m³	VLA-EC: 15 ppm VLA-EC: 37 mg/m³ VLA-ED: 10 ppm VLA-ED: 25 mg/m³	MAK: 10 ppm MAK: 25 mg/m³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³ TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin
Isopropyl alcohol 67-63-0		STEL: 500 ppm STEL: 1250 mg/m³ TWA: 400 ppm TWA: 999 mg/m³	VLCT: 400 ppm VLCT: 980 mg/m³	VLA-EC: 400 ppm VLA-EC: 1000 mg/m³ VLA-ED: 200 ppm VLA-ED: 500 mg/m³	MAK: 200 ppm MAK: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³ TWA: 200 ppm TWA: 500 mg/m³

Component	Italië	Portugal	Nederland	Finland	Denemarken
Ethyl alcohol 64-17-5 (25)		TWA: 1000 ppm	Skin STEL: 1900 mg/m³ TWA: 260 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Acetic acid 64-19-7 (4.8)		STEL: 15 ppm TWA: 10 ppm		TWA: 5 ppm TWA: 13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³	TWA: 10 ppm TWA: 25 mg/m³
Methyl alcohol 67-56-1 (1.4)	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0 (1.4)		STEL: 400 ppm TWA: 200 ppm		TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³	TWA: 200 ppm TWA: 490 mg/m³

Chemische naam	Oostenrijk	Zwitserland	Polen	Noorwegen	Ierland
Ethyl alcohol 64-17-5	STEL 2000 ppm STEL 3800 mg/m³ MAK: 1000 ppm MAK: 1900 mg/m³	STEL: 1000 ppm STEL: 1920 mg/m³ MAK: 500 ppm MAK: 960 mg/m³	NDS: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Zinc sulfate 7733-02-0		STEL: 0.4 mg/m³ STEL: 4 mg/m³ MAK: 0.1 mg/m³ MAK: 2 mg/m³			
Acetic acid 64-19-7	STEL 20 ppm STEL 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	STEL: 20 ppm STEL: 50 mg/m³ MAK: 10 ppm MAK: 25 mg/m³	NDSCh: 30 mg/m³ NDS: 15 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 20 ppm STEL: 37.5 mg/m³	TWA: 10 ppm TWA: 25 mg/m³ STEL: 15 ppm STEL: 37 mg/m³

Methyl alcohol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³ Skin	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin
Isopropyl alcohol 67-63-0	STEL 800 ppm STEL 2000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	STEL: 400 ppm STEL: 1000 mg/m³ MAK: 200 ppm MAK: 500 mg/m³	NDSCh: 1200 mg/m³ NDS: 900 mg/m³ Skin	TWA: 100 ppm TWA: 245 mg/m³ STEL: 150 ppm STEL: 306.25 mg/m³	TWA: 200 ppm STEL: 400 ppm Skin

Afgeleide doses zonder effect (DNEL) Geen gegevens beschikbaar

Voorspelde concentraties zonder effect (PNEC) Geen gegevens beschikbaar

8.2 Maatregelen ter beheersing van blootstelling

Technische maatregelen Voor geschikte ventilatie zorgen, vooral in gesloten ruimten.

Persoonlijke beschermingsmiddelen

Bescherming van de ogen Nauw aansluitende veiligheidsstofbril.

Bescherming van de handen Beschermende handschoenen.

Huid- en lichaamsbescherming Wear impervious rubber clothing if needed to prevent contact with liquid material.

Bescherming van de ademhalingswegen Bij blootstelling aan concentraties boven de MAC-waarde moet toereikende, goedgekeurde adembescherming worden gedragen.

Hygiënische maatregelen Gebruiken volgens goede industriële hygiëne en veiligheid.

Beheersing van milieublootstelling Voorkom dat product in riolering komt.

9. Fysische en chemische eigenschappen

9.1 Informatie over fysische en chemische basiseigenschappen

Fysische toestand vloeibaar

Voorkomen Geen gegevens beschikbaar

Geur Geen gegevens beschikbaar

Kleur kleurloos

Geurdrempelwaarde Geen gegevens beschikbaar

Eigenschap	Waarden	Opmerkingen • Methods
pH		Geen gegevens beschikbaar
Smelt-/vriespunt		Geen gegevens beschikbaar
Kookpunt/kooktraject	85 °C / 185 °F	niet van toepassing
Vlampunt	16 °C / 61 °F	niet van toepassing
Verdampingssnelheid		Geen gegevens beschikbaar
Ontvlambaarheid (vast, gas)		Geen gegevens beschikbaar
Ontvlambaarheidgrenzen in lucht		Geen gegevens beschikbaar
hoogste vlampunt		
laagste vlampunt		
Dampspanning		Geen gegevens beschikbaar
Dampdichtheid		Geen gegevens beschikbaar
Soortelijk gewicht		Geen gegevens beschikbaar
Oplosbaarheid in water		Oplosbaar in water
Oplosbaarheid in andere oplosmiddelen		Geen gegevens beschikbaar
Verdelingscoëfficiënt: n-octanol/water		Geen gegevens beschikbaar
Zelfontbrandingstemperatuur		Geen gegevens beschikbaar
Ontledingstemperatuur		Geen gegevens beschikbaar
Viscositeit, kinematisch		Geen gegevens beschikbaar
Viscositeit, dynamisch		

Ontploffingseigenschappen	Geen gegevens beschikbaar
Oxiderende eigenschappen	Geen gegevens beschikbaar

9.2 Overige informatie

Verwekingspunt	Geen gegevens beschikbaar
Moleculair gewicht	Geen gegevens beschikbaar
VOS (vluchtige organische stoffen) gehalte (%)	Geen gegevens beschikbaar
Dichtheid	Geen gegevens beschikbaar
Bulk soortelijk gewicht	Geen gegevens beschikbaar

10. Stabiliteit en reactiviteit

10.1 Reactiviteit

10.2 Chemische stabiliteit

Stabiel onder normale omstandigheden.

10.3 Mogelijke gevaarlijke reacties

10.4 Te vermijden omstandigheden

Warmte, vlammen en vonken.

10.5 Chemisch op elkaar inwerkende materialen

Sterke basen. Oxidatiemiddelen.

10.6 Gevaarlijke ontledingsproducten

Geen, bij normaal gebruik.

11. TOXICOLOGISCHE INFORMATIE

11.1 Informatie over toxicologische effecten

Acute toxiciteit

Productinformatie	Het product levert op basis van bekende of geleverde informatie geen gevaar voor acute toxiciteit.
Inademing	Over dit product zijn geen gegevens beschikbaar.
Aanraking met de ogen	Over dit product zijn geen gegevens beschikbaar.
Aanraking met de huid	Over dit product zijn geen gegevens beschikbaar.
Inslikken	Over dit product zijn geen gegevens beschikbaar.
Acute toxiciteit	59.5% van het mengsel bestaat uit bestanddelen waarvan over de toxiciteit niets bekend is.

The following values are calculated based on chapter 3.1 of the GHS document:

Oraal	1,339.00 mg/kg
Huid	4,818.00 mg/kg
Inademing	
gas	3,344.00 mg/l
Nevels	0.20 mg/l
Damp	106.70 mg/l

Chemische naam	LD50 oraal	LD50 huid	LC50 Inademen
Ethyl alcohol	7060 mg/kg (Rat)		124.7 mg/L (Rat) 4 h
Zinc sulfate	500 mg/kg (Rat)		
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h
Methyl alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h 64000 ppm (Rat) 4 h
Isopropyl alcohol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Huidcorrosie/-irritatie Geen gegevens beschikbaar.

Oogletsel/-irritatie Geen gegevens beschikbaar.

Sensibilisering Geen gegevens beschikbaar.

Mutageniciteit in geslachtscellen Geen gegevens beschikbaar.

Kankerverwekkendheid Geen gegevens beschikbaar.

Giftigheid voor de voortplanting Geen gegevens beschikbaar.

Specifieke doelorgaantoxiciteit - eenmalige blootstelling Geen gegevens beschikbaar.

Specifieke doelorgaantoxiciteit - herhaalde blootstelling Geen gegevens beschikbaar.

Aspiratiegevaar Geen gegevens beschikbaar.

12. Ecologische informatie

12.1 Toxiciteit

Ecotoxiciteitseffecten Vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken.

Chemische naam	Toxiciteit voor algen	Toxiciteit voor vissen	Toxiciteit voor dafnia's en andere ongewervelde waterdieren
Ethyl alcohol		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through >100: 96 h Pimephales promelas mg/L LC50 static	10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static 9268 - 14221: 48 h Daphnia magna mg/L LC50

Zinc sulfate	0.056: 72 h Pseudokirchneriella subcapitata mg/L EC50 static 2.4: 96 h Chlorella vulgaris mg/L EC50 64.8: 72 h Chlorella vulgaris mg/L EC50	0.03-0.05: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.06: 96 h Pimephales promelas mg/L LC50 static 0.15: 96 h Cyprinus carpio mg/L LC50 semi-static 0.162: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 0.168-0.25: 96 h Pimephales promelas mg/L LC50 semi-static 0.218-0.42: 96 h Pimephales promelas mg/L LC50 flow-through 0.23-0.48: 96 h Pimephales promelas mg/L LC50 0.34-0.93: 96 h Oncorhynchus mykiss mg/L LC50 static 0.48-1.72: 96 h Poecilia reticulata mg/L LC50 static 0.63: 96 h Poecilia reticulata mg/L LC50 16.85-27.18: 96 h Cyprinus carpio mg/L LC50 static 3-4.6: 96 h Lepomis macrochirus mg/L LC50 flow-through 3.55-6.32: 96 h Lepomis macrochirus mg/L LC50 static 49.23-64.16: 96 h Poecilia reticulata mg/L LC50 semi-static	0.538 - 0.908: 48 h Daphnia magna mg/L EC50 Static 0.75: 48 h Daphnia magna mg/L EC50
Acetic acid		75: 96 h Lepomis macrochirus mg/L LC50 static 79: 96 h Pimephales promelas mg/L LC50 static	47: 24 h Daphnia magna mg/L EC50 65: 48 h Daphnia magna mg/L EC50 Static
Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Isopropyl alcohol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50

12.2 Persistentie en afbreekbaarheid

Geen gegevens beschikbaar.

12.3 Bioaccumulatie

Geen gegevens beschikbaar.

Chemische naam	log Pow
Ethyl alcohol	0
Acetic acid	0
Methyl alcohol	-0.77
Isopropyl alcohol	0.05

12.4 Mobiliteit in de bodem

Mobiliteit
Geen gegevens beschikbaar.

12.5 Resultaten van PBT- en zPzB-beoordeling

Geen gegevens beschikbaar.

12.6 Andere schadelijke effecten.

13. Instructies voor verwijdering

13.1 Afvalverwerkingsmethoden

Afval van residuen / niet-gebruikte producten	Verwijderen als gevaarlijk afval volgens plaatselijke en landelijke voorschriften. Mag niet in het milieu vrijkomen.
Verontreinigde verpakking	Verwijderen volgens plaatselijke voorschriften. Lege containers niet hergebruiken.

14. Informatie met betrekking tot het vervoer

ICAO/IATA	Flammable Liquid, Corrosive, n.o.s.
14.1. UN/ID Nr	2924
14.2. Juiste ladingnaam overeenkomstig de modelreglementen van de VN	Ethanol, Acetic Acid
14.3. Gevarenklasse	3
Ondergeschikte gevarenklasse	8
14.4. Verpakkingsgroep	II
Beschrijving	Para-Pak® Zn-PVA
14.5. Bijzondere Bepalingen	geen
14.6. Opmerking	Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

15. Regelgeving

15.1 Specifieke veiligheids-, gezondheids- en milieureglementen en -wetgeving voor de stof of het mengsel

Chemische naam	French RG number
Ethyl alcohol	RG 84
Methyl alcohol	RG 84
Isopropyl alcohol	RG 84

Internationale voorraadlijsten

TSCA	Voldoet aan
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
China	-
AICS	-
KECL	-

Opschrift

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory (Inventaris in Sectie 8(b) van de Amerikaanse wet inzake het beheer van toxische stoffen)
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances (Europese inventaris van bestaande chemische handelsstoffen/Europese lijst van stoffen waarvan kennisgeving is gedaan)
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List (Canadese lijst van chemische stoffen)
PICCS - Philippines Inventory of Chemicals and Chemical Substances (Filippijnse inventaris van chemische stoffen)
ENCS - Japan Inventory of Existing and New Chemical Substances (Japanse inventaris van bestaande en nieuwe chemische stoffen)
IECSC - China Inventory of Existing Chemical Substances (Chinese inventaris van bestaande chemische stoffen)
AICS - Australian Inventory of Chemical Substances (Australische inventaris van chemische stoffen)
KECL - Korean Inventory of Existing and Evaluated Chemical Substances (Koreaanse inventaris van bestaande en beoordeelde chemische stoffen)

15.2 Chemischeveiligheidsbeoordeling

Geen gegevens beschikbaar

16. Overige informatie

Volledige tekst van R-zinnen waarnaar in rubrieken 2 en 3 wordt verwezen
R41 - Gevaar voor ernstig oogletsel
R22 - Schadelijk bij opname door de mond
R35 - Veroorzaakt ernstige brandwonden
R10 - Ontvlambaar
R11 - Licht ontvlambaar
R67 - Dampen kunnen slaperigheid en duizeligheid veroorzaken
R36 - Irriterend voor de ogen
R50/53 - Zeer vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken
R39/23/24/25 - Vergiftig: gevaar voor ernstige onherstelbare effecten bij inademing, aanraking met de huid en opname door de mond
R23/24/25 - Vergiftig bij inademing, opname door de mond en aanraking met de huid
R51/53 - Vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken

Volledige tekst van H-zinnen zoals vermeld in paragraaf 2 en 3
H314 - Veroorzaakt ernstige brandwonden en oogletsel
H226 - Ontvlambare vloeistof en damp
H301 - Giftig bij inslikken
H311 - Giftig bij contact met de huid
H331 - Giftig bij inademing
H370 - Veroorzaakt schade aan organen (a,b,c) bij inademing
H225 - Licht ontvlambare vloeistof en damp
H319 - Veroorzaakt ernstige oogirritatie
H336 - Kan slaperigheid of duizeligheid veroorzaken
H302 - Schadelijk bij inslikken
H318 - Veroorzaakt ernstig oogletsel
H400 - Zeer giftig voor in het water levende organismen
H410 - Zeer giftig voor in het water levende organismen, met langdurige gevolgen
H302 - Schadelijk bij inslikken
H314 - Veroorzaakt ernstige brandwonden en oogletsel
H330 - Dodelijk bij inademing.
H350 - Kan kanker veroorzaken
H410 - Zeer giftig voor in het water levende organismen, met langdurige gevolgen

Datum van uitgifte	01-aug-2013
Herzieningsdatum	01-aug-2013
Herzieningsnotitie	niet van toepassing.

Dit veiligheidsinformatieblad voldoet aan de eisen van Verordening (EG) Nummer 1907/2006

Vrijwaringclausule
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

Einde van het Veiligheidsinformatieblad

HealthLink® A Family of Medical Products
Joining Forces to Serve the Healthcare Community
CLOROX HEALTHCARE®

Safety Data Sheet

Potassium Hydroxide Solution, 20%

Revision Date 1/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Potassium Hydroxide, 20%
Product code: 400535, 400536

Supplier: HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM

Synonym: None.
Material uses: Laboratory Reagent.
Validation date: 1/15/2015
In case of emergency: 800-424-9300 CHEMTREC (USA)
24 Hours/Day: 7 Days/Week

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA, GHS Classification: Acute toxicity, Oral, H301; Skin irritation, H315; Eye irritation, H319

GHS Label Elements

Corrosive Liquid, Danger!
Will burn eyes and skin. Causes respiratory tract burns, toxic if swallowed, will cause skin irritation, will cause serious eye irritation, harmful to aquatic life
Globally Harmonized System (GHS).

HMIS Classification
Health hazard: 2
Flammability: 0
Physical hazards: 0

NFPA Rating
Health hazard: 2
Fire: 0
Reactivity Hazard: 0

Potential Health Effects
Inhalation - May be harmful if inhaled. Causes respiratory tract burns and irritation.
Skin - May be harmful if absorbed through skin. Causes skin burns and irritation.
Eyes – Will burn eyes on contact
Ingestion – Harmful/toxic if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	CAS number	% by weight
Water	7732-18-5	~80
Potassium Hydroxide	1310-58-3	20

4. FIRST AID MEASURES

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention if symptoms occur.

Skin contact: In case of contact, flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention if symptoms occur.

Inhalation: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms occur.

Ingestion: Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

5. FIRE-FIGHTING MEASURES

Flammability of the product: Product is not flammable

Extinguishing media: Use an extinguishing agent suitable for the surrounding fire

Not suitable: None known.

Special exposure hazards: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Hazardous thermal decomposition products: Oxides of potassium

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Do not breathe vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).

Environmental cautions: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container

7. HANDLING AND STORAGE

Handling: Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Storage: Store in accordance with local regulations. Store in a segregated and approved area. Store in original container, protected from direct sunlight. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Consult local authorities for acceptable exposure limits. CEIL ACGIH, NIOSH, 2mg/m_3

Engineering measures: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protection

Respiratory: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Hands: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Eyes: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. Recommended: splash goggles

Skin: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Color: Colorless
Odor: Odorless.
pH: >12
Boiling/condensation point: >100°C (212°F).
Melting/freezing point: Not available.
Relative density: ~1.07
Vapor pressure: Not available.
Vapor density: Not available.
Odor threshold: Not available.
Evaporation rate: Not available
VOC : 0 % (w/w)
Solubility: Complete in water

10. STABILITY AND REACTIVITY

Chemical stability: The product is stable.
Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid: If mixed with strong acids will cause splattering and heat, metals
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

Carcinogenicity: No known significant effects
Mutagenicity: No known significant effects
Teratogenicity: No known significant effects

Material is destructive to tissue of the mucous membrane and upper respiratory tract including eyes and skin.

12. ECOLOGICAL INFORMATION

Environmental effects: Not biodegradable as it is not an organic compound capable of decomposition. However, the material would be neutralized by acidity present in the natural environment

Aquatic Toxicity: Depending on the volume, may cause shift in water pH outside the range of pH 5 to 10. This would be toxic to aquatic organisms.

13. DISPOSAL CONSIDERATIONS

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

DOT: IMDG: IATA: UN1814, Potassium Hydroxide Solution, Class 8, PG II

15. REGULATORY INFORMATION

United States RQ 1000 lbs

OS**HA Classification:** Meets criteria for hazardous material as defined by 29 CFR 1910.1200

U.S. Federal regulations: TSCA Listed on inventory CAS
SARA 302 RQ/TPQ 1000lbs/No products were found.
SARA 313: No chemicals for this mixture are reportable
Clean Air Act: No products were found.
Clean Water Act: CAS1310-56-3 is listed, not as a priority or toxic pollutant

DEA List I Chemicals (Precursor Chemicals): Not listed
DEA List II Chemicals (Essential Chemicals): Not listed

Massachusetts RTK: CAS1310-56-3 listed.
New Jersey RTK: CAS1310-56-3 listed.
Pennsylvania RTK CAS1310-56-3 listed.
California Prop 65 Not Listed

Canada
WHMIS (Canada): This product is listed on the Domestic Substance Act CAS1310-56-3
Canadian lists: CEPA Toxic substances: Class D1B Poisonous and infectious material-immediate and serious effects- Toxic, E-Corrosive

CEPA DSL / CEPA NDSL: All components are listed or exempted.
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

International regulations
International lists: **Australia inventory (AICS)**: All components are listed or exempted.

China inventory (IECSC): Not determined.
Japan inventory: All components are listed or exempted.
Korea inventory: All components are listed or exempted.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): All components are listed or exempted.

16. OTHER INFORMATION

National Fire Protection Association (U.S.A.)

Notice to reader

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HealthLink® A Family of Medical Products
Joining Forces to Serve the Healthcare Community
CLOROX HEALTHCARE®

Safety Data Sheet

Potassium Hydroxide Solution, 5%

Revision Date 1/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Potassium Hydroxide, 5%
Product code: 400504

Supplier: HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM

Synonym: None.
Material uses: Laboratory Reagent.
Validation date: 1/15/2015
In case of emergency: 800-424-9300 CHEMTREC (USA)
24 Hours/Day: 7 Days/Week

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA, GHS Classification: Acute toxicity, Oral, H301; Skin irritation, H315; Eye irritation, H319

GHS Label Elements

Corrosive Liquid, Danger!
Will burn eyes and skin. Causes respiratory tract burns, toxic if swallowed, will cause skin irritation, will cause serious eye irritation, harmful to aquatic life
Globally Harmonized System (GHS).

HMIS Classification
Health hazard: 2
Flammability: 0
Physical hazards: 0

NFPA Rating
Health hazard: 2
Fire: 0
Reactivity Hazard: 0

Potential Health Effects
Inhalation - May be harmful if inhaled. Causes respiratory tract burns and irritation.
Skin - May be harmful if absorbed through skin. Causes skin burns and irritation.
Eyes – Will burn eyes on contact
Ingestion – Harmful/toxic if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	CAS number	% by weight
Water	7732-18-5	~99
Potassium Hydroxide	1310-58-3	5

4. FIRST AID MEASURES

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention if symptoms occur.

Skin contact: In case of contact, flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention if symptoms occur.

Inhalation: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms occur.

Ingestion: Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

5. FIRE-FIGHTING MEASURES

Flammability of the product: Product is not flammable

Extinguishing media: Use an extinguishing agent suitable for the surrounding fire

Not suitable: None known.

Special exposure hazards: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Hazardous thermal decomposition products: Oxides of potassium

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Do not breathe vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).

Environmental cautions: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container

7. HANDLING AND STORAGE

Handling: Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Storage: Store in accordance with local regulations. Store in a segregated and approved area. Store in original container, protected from direct sunlight. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Consult local authorities for acceptable exposure limits. CEIL ACGIH, NIOSH, 2mg/m3

Engineering measures: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protection

Respiratory: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Hands: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Eyes: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. Recommended: splash goggles

Skin: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Color: Colorless
Odor: Odorless.
pH: >12
Boiling/condensation point: >100°C (212°F).
Melting/freezing point: Not available.
Relative density: ~1.07
Vapor pressure: Not available.
Vapor density: Not available.
Odor threshold: Not available.
Evaporation rate: Not available
VOC : 0 % (w/w)
Solubility: Complete in water

10. STABILITY AND REACTIVITY

Chemical stability: The product is stable.
Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid: If mixed with strong acids will cause splattering and heat, metals
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

Carcinogenicity: No known significant effects
Mutagenicity: No known significant effects
Teratogenicity: No known significant effects

Material is destructive to tissue of the mucous membrane and upper respiratory tract including eyes and skin.

12. ECOLOGICAL INFORMATION

Environmental effects: Not biodegradable as it is not an organic compound capable of decomposition. However, the material would be neutralized by acidity present in the natural environment

Aquatic Toxicity: Depending on the volume, may cause shift in water pH outside the range of pH 5 to 10. This would be toxic to aquatic organisms.

13. DISPOSAL CONSIDERATIONS

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

DOT: IMDG: IATA: UN1814, Potassium Hydroxide Solution, Class 8, PG II

15. REGULATORY INFORMATION

United States RQ 1000 lbs

OS**HA Classification:** Meets criteria for hazardous material as defined by 29 CFR 1910.1200

U.S. Federal regulations: TSCA Listed on inventory CAS
SARA 302 RQ/TPQ 1000lbs/No products were found.
SARA 313: No chemicals for this mixture are reportable
Clean Air Act: No products were found.
Clean Water Act: CAS1310-56-3 is listed, not as a priority or toxic pollutant

DEA List I Chemicals (Precursor Chemicals): Not listed
DEA List II Chemicals (Essential Chemicals): Not listed

Massachusetts RTK: CAS1310-56-3 listed.
New Jersey RTK: CAS1310-56-3 listed.
Pennsylvania RTK CAS1310-56-3 listed.
California Prop 65 Not Listed

Canada
WHMIS (Canada): This product is listed on the Domestic Substance Act CAS1310-56-3
Canadian lists: CEPA Toxic substances: Class D1B Poisonous and infectious material-immediate and serious effects- Toxic, E-Corrosive

CEPA DSL / CEPA NDSL: All components are listed or exempted.
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Korea inventory: All components are listed or exempted.
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CLOROX HEALTHCARE®

Safety Data Sheet

Potassium Hydroxide Solution, 10%

Revision Date 1/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Potassium Hydroxide, 10%
Product code: 400510, 400511, 400530, 400531, 1815

Supplier:
HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM

Synonym: None.
Material uses: Laboratory Reagent.
Validation date: 1/15/2015
In case of emergency: 800-424-9300 CHEMTREC (USA)
24 Hours/Day: 7 Days/Week

2. HAZARDS IDENTIFICATION

Emergency Overview
OSHA, GHS Classification: Acute toxicity, Oral, H301; Skin irritation, H315; Eye irritation, H319

GHS Label Elements

Corrosive Liquid, Danger!
Will burn eyes and skin. Causes respiratory tract burns, toxic if swallowed, will cause skin irritation, will cause serious eye irritation, harmful to aquatic life
Globally Harmonized System (GHS).

HMIS Classification
Health hazard: 2
Flammability: 0
Physical hazards: 0

NFPA Rating
Health hazard: 2
Fire: 0
Reactivity Hazard: 0

Potential Health Effects
Inhalation - May be harmful if inhaled. Causes respiratory tract burns and irritation.
Skin - May be harmful if absorbed through skin. Causes skin burns and irritation.
Eyes – Will burn eyes on contact
Ingestion – Harmful/toxic if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	CAS number	% by weight
Water	7732-18-5	~99
Potassium Hydroxide	1310-58-3	10

4. FIRST AID MEASURES

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention if symptoms occur.

Skin contact: In case of contact, flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention if symptoms occur.

Inhalation: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms occur.

Ingestion: Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

5. FIRE-FIGHTING MEASURES

Flammability of the product: Product is not flammable

Extinguishing media: Use an extinguishing agent suitable for the surrounding fire

Not suitable: None known.

Special exposure hazards: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Hazardous thermal decomposition products: Oxides of potassium

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Storage: Store in accordance with local regulations. Store in a segregated and approved area. Store in original container, protected from direct sunlight. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Consult local authorities for acceptable exposure limits. CEIL ACGIH, NIOSH, 2mg/m_3

Engineering measures: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

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Skin: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Color: Colorless
Odor: Odorless.
pH: >12
Boiling/condensation point: >100°C (212°F).
Melting/freezing point: Not available.
Relative density: ~1.07
Vapor pressure: Not available.
Vapor density: Not available.
Odor threshold: Not available.
Evaporation rate: Not available
VOC : 0 % (w/w)
Solubility: Complete in water

10. STABILITY AND REACTIVITY

Chemical stability: The product is stable.
Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
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Conditions to avoid: If mixed with strong acids will cause splattering and heat, metals
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15. REGULATORY INFORMATION

United States RQ 1000 lbs

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DEA List II Chemicals (Essential Chemicals): Not listed

Massachusetts RTK: CAS1310-56-3 listed.
New Jersey RTK: CAS1310-56-3 listed.
Pennsylvania RTK CAS1310-56-3 listed.
California Prop 65 Not Listed

Canada
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Canadian lists: CEPA Toxic substances: Class D1B Poisonous and infectious material-immediate and serious effects- Toxic, E-Corrosive

CEPA DSL / CEPA NDSL: All components are listed or exempted.
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International regulations
International lists:
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China inventory (IECSC): Not determined.
Japan inventory: All components are listed or exempted.
Korea inventory: All components are listed or exempted.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): All components are listed or exempted.

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National Fire Protection Association (U.S.A.)

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Kit SDS Cover Sheet

Doc. ID: 33550-75: Rev. AG
Revised (year/month/day) 2015/04/27

Product Information

Product Name	PROGESTERONE
Part Number	33550
Series Name	ACCESS®

Components

Description	PMP/Conjugate (Compartment R1a) Progesterone Blocker (Compartment R1b) Progesterone Antibody (Compartment R1c)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33550-75 Rev. AG
Revised (year/month/day) 2015/04/27

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PMP/Conjugate (Compartment R1a)

Part Number Component of P/N 33550

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.016 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.4	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Global SDS – English

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL

Sucrose is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Sucrose is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

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Section 16 Other Information (Continued)

	T+ - Very toxic
	R28 Very toxic if swallowed.
	R32 Contact with acids liberates very toxic gas.
	R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33550-75 Rev. AG
Revised (year/month/day) 2015/04/27

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Progesterone Blocker (Compartment R1b)

Part Number Component of P/N 33550

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Acetic Acid

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.
Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Acetic Acid CAS # 64-19-7 EINECS # 200-580-7 Index # 607-002-00-6	0.1 - 0.5	C;R10-35	Flam. Liq. 3 Skin Corr. 1A H226; H314	Flam. Liq. 3 Skin Corr. 1A H226; H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

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Section 4 First Aid Measures (Continued)

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

Causes mild skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Wear protective gloves, protective clothing and eye/face protection.

Observe general safety guidelines for protection; avoid eye and skin contact.

This product contains a material of animal origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA

ACGIH

Acetic Acid CAS # 64-19-7	15 ppm STEL; 10 ppm TWA

DFG MAK

Acetic Acid CAS # 64-19-7	20 ppm Peak; 50 mg/m3 Peak; 10 ppm TWA MAK; 25 mg/m3 TWA MAK

Ireland

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA; 15 ppm STEL; 37 mg/m3 STEL

IOELVs None established

NIOSH

Acetic Acid CAS # 64-19-7	50 ppm IDLH; 15 ppm STEL; 37 mg/m3 STEL; 10 ppm TWA; 25 mg/m3 TWA

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Global SDS – English

Section 8 Exposure Controls and Personal Protection (Continued)

Japan

Acetic Acid CAS # 64-19-7	10 ppm OEL; 25 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.014 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	5.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Acetic Acid 0.074 ppm geometric mean air odor threshold = (detectable)		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		No further relevant information available.
10.4	**Conditions to Avoid**	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing significant hazards would be expected from this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Acetic Acid CAS # 64-19-7	Inhalation LC50 Rat 11.4 mg/L 4 h; Oral LD50 Rat 3310 mg/kg; Dermal LD50 Rabbit 1060 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.

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Section 11 Toxicological Information (Continued)

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Acetic Acid CAS # 64-19-7	96 h LC50 Pimephales promelas: 79 mg/L [static]; 96 h LC50 Lepomis macrochirus: 75 mg/L [static]
Microtox	No information available.

Water Flea

Acetic Acid CAS # 64-19-7	24 h EC50 Daphnia magna: 47 mg/L; 48 h EC50 Daphnia magna: 65 mg/L [Static]
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 Acetic Acid is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Acetic Acid is listed.

New Jersey Dept. of Health RTK List

Acetic Acid is listed.

Pennsylvania RTK Acetic Acid is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetic Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive

R10 Flammable.

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Section 16 Other Information (Continued)

	R35 Causes severe burns. Flam. Liq. 3 - Flammable Liquids, Category 3 Skin Corr. 1A - Skin Corrosion Category 1A H226 - Flammable liquid and vapour. H314 - Causes severe skin burns and eye damage.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: 33550-75 Rev. AG
Revised (year/month/day) 2015/04/27

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Progesterone Antibody (Compartment R1c)

Part Number Component of P/N 33550

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Acetic Acid

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.
Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Acetic Acid CAS # 64-19-7 EINECS # 200-580-7 Index # 607-002-00-6	< 1	C;R10-35	Flam. Liq. 3 Skin Corr. 1A H226; H314	Flam. Liq. 3 Skin Corr. 1A H226; H314	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

Causes mild skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

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Section 6 Accidental Release Measures (Continued)

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA

ACGIH

Acetic Acid CAS # 64-19-7	15 ppm STEL; 10 ppm TWA
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Acetic Acid CAS # 64-19-7	20 ppm Peak; 50 mg/m3 Peak; 10 ppm TWA MAK; 25 mg/m3 TWA MAK
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA; 15 ppm STEL; 37 mg/m3 STEL
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

Acetic Acid CAS # 64-19-7	50 ppm IDLH; 15 ppm STEL; 37 mg/m3 STEL; 10 ppm TWA; 25 mg/m3 TWA

Japan

Acetic Acid CAS # 64-19-7	10 ppm OEL; 25 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.011 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined

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Global SDS – English

Section 9 Physical and Chemical Properties (Continued)

pH	4.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Acetic Acid 0.074 ppm geometric mean air odor threshold = (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Acetic Acid CAS # 64-19-7	Inhalation LC50 Rat 11.4 mg/L 4 h; Oral LD50 Rat 3310 mg/kg; Dermal LD50 Rabbit 1060 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

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Section 11 Toxicological Information (Continued)

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Acetic Acid CAS # 64-19-7	96 h LC50 Pimephales promelas: 79 mg/L [static]; 96 h LC50 Lepomis macrochirus: 75 mg/L [static]
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	
	Acetic Acid CAS # 64-19-7	24 h EC50 Daphnia magna: 47 mg/L; 48 h EC50 Daphnia magna: 65 mg/L [Static]
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetic Acid is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Acetic Acid is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetic Acid is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK
Acetic Acid is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List
Acetic Acid
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3
C - Corrosive
N - Dangerous for the environment

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Section 16 Other Information (Continued)

T+ - Very toxic
R10 Flammable.
R35 Causes severe burns.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Flam. Liq. 3 - Flammable Liquids, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
H226 - Flammable liquid and vapour.
H300 - Fatal if swallowed.
H314 - Causes severe skin burns and eye damage.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Doc. ID: 33530-75: Rev. AH
Revised (year/month/day) 2015/04/15

Product Information

Product Name	PROLACTIN
Part Number	33530
Series Name	ACCESS®

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Prolactin Particles (Well R1a)
Prolactin Conjugate (Well R1b)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 33530-75 Rev. AH
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Prolactin Particles (Well R1a)

Part Number Component of P/N 33530

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.05	**Partition coefficient: n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not available	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes skin irritation.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	Causes eye irritation
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Selenite is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Potassium Nitrate is listed.
Sodium Selenite is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Potassium Nitrate is listed.
Sodium Selenite is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Potassium Nitrate is listed.
Sodium Selenite is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.

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Section 16 Other Information (Continued)

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H300 - Fatal if swallowed.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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For further information, please contact your local Beckman Coulter, Inc. representative.

WHILE BECKMAN COULTER, INC. BELIEVES THE INFORMATION CONTAINED HEREIN IS VALID AND ACCURATE, MAKES NO WARRANTY OR REPRESENTATION AS TO ITS VALIDITY, ACCURACY, OR CURRENCY. BECKMAN COULTER, INC. SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR USE OF EITHER THIS INFORMATION OR MATERIALS TO WHICH IT APPLIES. DISPOSAL OF HAZARDOUS MATERIALS MAY BE SUBJECT TO LOCAL LAWS OR REGULATIONS.

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33530-75 Rev. AH
Revised (year/month/day) 2015/04/15

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Prolactin Conjugate (Well R1b)

Part Number Component of P/N 33530

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22-43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.007 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes eye irritation

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Section 11 Toxicological Information (Continued)

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

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Section 16 Other Information (Continued)

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: IM2520-75: Rev. AB
Revised (year/month/day) 2015/05/04

Product Information

Product Name PSA free IRMA

Part Number IM2520

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

125I-labeled anti-PSA monoclonal antibody tracer
PSA free IRMA Calibrator 1 to 5
PSA free IRMA Control 1 and 2
Wash Solution (500x)
PSA free IRMA Calibrator Zero

Transport Information

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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SAFETY DATA SHEET

Doc. ID: IM2520-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name 125I-labeled anti-PSA monoclonal antibody tracer

Part Number Component of P/N IM2520

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Green; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

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Section 4 First Aid Measures (Continued)

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of all waste material in accordance with local and facility guidelines.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Radioactive material is subject to the regulations of each country.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.00 @20°C
Color	Green	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not applicable	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Global SDS – English

Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid — Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure — Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation — No data available.

Serious eye damage/eye irritation — No data available.

Respiratory/skin sensitization — No data available.

Carcinogenicity — This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity — No data available.

Reproductive Toxicity — No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	2910	2910	2910	2910	PIN - 2910
14.2	Shipping Name	Radioactive Material, excepted package-limited quantity of material				
14.3	Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
14.4	Packing Group					
	Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Additional information					
	IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	161	Not applicable	161
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

Iodine 125 has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 2910

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.

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Section 16 Other Information (Continued)

	R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2520-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PSA free IRMA Calibrator 1 to 5

Part Number Component of P/N IM2520

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Edetic Acid is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Edetic Acid is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List
Edetic Acid is listed.
Sodium Azide is listed.

Pennsylvania RTK
Edetic Acid is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List
Sodium Azide

Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

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Section 16 Other Information (Continued)

	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2520-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PSA free IRMA Control 1 and 2

Part Number Component of P/N IM2520

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Lyophilized - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.4	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2520-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Wash Solution (500x)

Part Number Component of P/N IM2520

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

DFG MAK None established

Ireland None established

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Global SDS – English

Section 8 Exposure Controls and Personal Protection (Continued)

	IOELVs	None established
	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	Not available	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard	No data available.
Other Information	No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

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Section 16 Other Information (Continued)

NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM2520-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PSA free IRMA Calibrator Zero

Part Number Component of P/N IM2520

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Edetic Acid is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Edetic Acid is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List
Edetic Acid is listed.
Sodium Azide is listed.

Pennsylvania RTK
Edetic Acid is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List
Sodium Azide

Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

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Section 16 Other Information (Continued)

	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: IM1950-75: Rev. AB
Revised (year/month/day) 2015/05/04

Product Information

Product Name PSA total IRMA

Part Number IM1950

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Monoclonal 125I-labelled anti-PSA antibody
PSA Total IRMA Calibrator 1 to 5
PSA Total IRMA Control 1 and 2
Wash Solution (500x)
PSA Total IRMA Calibrator Zero

Transport Information

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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SAFETY DATA SHEET

Doc. ID: IM1950-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Monoclonal 125I-labelled anti-PSA antibody

Part Number Component of P/N IM1950

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Reddish-brown; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

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Section 4 First Aid Measures (Continued)

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of all waste material in accordance with local and facility guidelines.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Radioactive material is subject to the regulations of each country.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Reddish-brown	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not applicable	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid — Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	2910	2910	2910	2910	PIN - 2910
14.2	Shipping Name	Radioactive Material, excepted package-limited quantity of material				
14.3	Hazard Class	7 Radioactive Material	7 Radioactive material	7 Radioactive material	7 Radioactive material	7 Radioactive Materials
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
14.4	Packing Group					
	Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Additional information					
	IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	161	Not applicable	161
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

Iodine 125 has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Radioactive

R

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 2910

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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Section 16 Other Information (Continued)

	Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
	Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
	H300 - Fatal if swallowed.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1950-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PSA Total IRMA Calibrator 1 to 5

Part Number Component of P/N IM1950

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Edetic Acid is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Edetic Acid is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Edetic Acid is listed.
Sodium Azide is listed.

Pennsylvania RTK

Edetic Acid is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic

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Section 16 Other Information (Continued)

R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1950-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PSA Total IRMA Control 1 and 2

Part Number Component of P/N IM1950

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Lyophilized - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.4	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1950-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Wash Solution (500x)

Part Number Component of P/N IM1950

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

DFG MAK None established

Ireland None established

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Global SDS – English

Section 8 Exposure Controls and Personal Protection (Continued)

	IOELVs	None established
	NIOSH	None established
	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	Not available	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

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Section 16 Other Information (Continued)

NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1950-75 Rev. AB
Revised (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name PSA Total IRMA Calibrator Zero

Part Number Component of P/N IM1950

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Edetic Acid is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Edetic Acid is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Edetic Acid is listed.
Sodium Azide is listed.

Pennsylvania RTK

Edetic Acid is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic

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Section 16 Other Information (Continued)

	R28 Very toxic if swallowed. R32 Contact with acids liberates very toxic gas. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 H300 - Fatal if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

PURELL® Advanced Hand Sanitizer E3 Rated Gel

Version	Revision Date:	MSDS Number:	Date of last issue: 12/19/2014
1.3	02/10/2015	36432-00004	Date of first issue: 12/11/2014

SECTION 1. IDENTIFICATION

Product name : PURELL® Advanced Hand Sanitizer E3 Rated Gel

Manufacturer or supplier's details

Company name of supplier : GOJO Industries, Inc.

Address : One GOJO Plaza, Suite 500
Akron OH 44311

Telephone : 1 (330) 255-6000

Emergency telephone : 1-800-424-9300 CHEMTREC

Recommended use of the chemical and restrictions on use

Recommended use : Hand Sanitizer

Restrictions on use : This is a personal care or cosmetic product that is safe for consumers and other users under normal and reasonably foreseeable use. Cosmetics and consumer products, specifically defined by regulations around the world, are exempt from the requirement of an SDS for the consumer. While this material is not considered hazardous, this SDS contains valuable information critical to the safe handling and proper use of the product for industrial workplace conditions as well as unusual and unintended exposures such as large spills. This SDS should be retained and available for employees and other users of this product. For specific intended-use guidance, please refer to the information provided on the package or instruction sheet.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3

Eye irritation : Category 2A

GHS Label element

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H226 Flammable liquid and vapor.

H319 Causes serious eye irritation.

Precautionary Statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical Name	CAS-No.	Concentration (%)
Ethanol	64-17-5	>= 50 - < 70
Propan-2-ol	67-63-0	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes serious eye irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Dry chemical Carbon dioxide (CO2)
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions,	:	Remove all sources of ignition.

protective equipment and emergency procedures		Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mists with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use with local exhaust ventilation. Use only in an area equipped with explosion proof exhaust ventilation.
Advice on safe handling	:	Do not breathe vapors or spray mist. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice. Non-sparking tools should be used. Keep container tightly closed. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Keep tightly closed.

Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m3	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m3	OSHA Z-1
		STEL	1,000 ppm	ACGIH
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		TWA	400 ppm 980 mg/m3	NIOSH REL
		ST	500 ppm 1,225 mg/m3	NIOSH REL
		TWA	400 ppm 980 mg/m3	OSHA Z-1

Biological occupational exposure limits

Ingredients	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work-week	40 mg/l	ACGIH BEI

Engineering measures : Minimize workplace exposure concentrations.
Use only in an area equipped with explosion proof exhaust ventilation.
Use with local exhaust ventilation.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Impervious gloves

Material : Flame retardant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Wear the following personal protective equipment:
Flame retardant antistatic protective clothing.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear

Odor : alcohol-like

Odor Threshold	:	No data available
pH	:	6.5 - 8.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	24 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	0.88 g/cm3
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	The substance or mixture is not classified self-reactive.
Viscosity		
Viscosity, kinematic	:	6,000 - 17,000 mm2/s (20 °C)
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.

Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Ingredients:

Ethanol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapor

Propan-2-ol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): 72.6 mg/l Exposure time: 4 h Test atmosphere: vapor
Acute dermal toxicity	:	LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Result: No skin irritation

Ingredients:

Ethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Propan-2-ol:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Ingredients:

Ethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Propan-2-ol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitization

Skin sensitization: Not classified based on available information.
Respiratory sensitization: Not classified based on available information.

Product:

Assessment: Does not cause skin sensitization.

Ingredients:

Ethanol:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

Propan-2-ol:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Ethanol:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: negative

Propan-2-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity

Not classified based on available information.

Ingredients:

Propan-2-ol:
Species: Rat
Application Route: inhalation (vapor)
Exposure time: 104 weeks
Method: OECD Test Guideline 451
Result: negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Ingredients:

Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion

Result: negative

STOT-single exposure

Not classified based on available information.

Ingredients:

Propan-2-ol:
Assessment: May cause drowsiness or dizziness.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Ingredients:

Ethanol:
Species: Rat
NOAEL: 2,400 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Propan-2-ol:
Species: Rat
NOAEL: 5000 ppm
Application Route: inhalation (vapor)
Exposure time: 104 w
Method: OECD Test Guideline 413

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 32.1 mg/l
Exposure time: 0.25 h

Propan-2-ol:
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

Toxicity to algae : ErC50 (Scenedesmus quadricauda (Green algae)): > 1,800 mg/l
Exposure time: 8 d

Toxicity to bacteria : EC50 (Pseudomonas putida): > 1,050 mg/l
Exposure time: 16 h

Persistence and degradability

Ingredients:

Ethanol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Propan-2-ol:
Biodegradability : Result: rapidly degradable

Bioaccumulative potential

Ingredients:

Ethanol:
Partition coefficient: n-octanol/water : log Pow: -0.35

Propan-2-ol:
Partition coefficient: n-octanol/water : log Pow: 0.05

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Dispose of as unused product.

Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not burn, or use a cutting torch on, the empty drum.

SECTION 14. TRANSPORT INFORMATION

International Regulation

UNRTDG

UN number	:	UN 1987
Proper shipping name	:	ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)
Class	:	3
Packing group	:	III
Labels	:	3

IATA-DGR

UN/ID No.	:	UN 1987
Proper shipping name	:	Alcohols, n.o.s. (Ethanol, Propan-2-ol)
Class	:	3
Packing group	:	III
Labels	:	Flammable Liquids
Packing instruction (cargo aircraft)	:	366
Packing instruction (passenger aircraft)	:	355

IMDG-Code

UN number	:	UN 1987
Proper shipping name	:	ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)
Class	:	3
Packing group	:	III
Labels	:	3
EmS Code	:	F-E, S-D
Marine pollutant	:	no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 1987
Proper shipping name	:	ALCOHOLS, N.O.S.
Class	:	3
Packing group	:	III
Labels	:	FLAMMABLE LIQUID
ERG Code	:	127

Marine pollutant : no

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : Fire Hazard
Acute Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Propan-2-ol	67-63-0	3.4086 %

US State Regulations

Pennsylvania Right To Know

Ethanol	64-17-5	50 - 70 %
Water	7732-18-5	30 - 50 %
Propan-2-ol	67-63-0	1 - 5 %

New Jersey Right To Know

Ethanol	64-17-5	50 - 70 %
Water	7732-18-5	30 - 50 %
Propan-2-ol	67-63-0	1 - 5 %

California Prop 65 This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

AICS : All ingredients listed or exempt.

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), NECSI (Taiwan), TSCA (USA)

SAFETY DATA SHEET

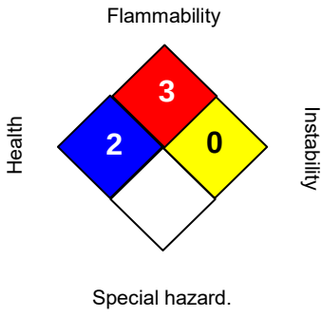
PURELL® Advanced Hand Sanitizer E3 Rated Gel

Version	Revision Date:	MSDS Number:	Date of last issue: 12/19/2014
1.3	02/10/2015	36432-00004	Date of first issue: 12/11/2014

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average
Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	02/10/2015

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8

Safetec
Infection Control & First Aid Products

SAFETY DATA SHEET

1. Identification

Product identifier RED Z®

Other means of identification Not available.

Recommended use Not available.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Manufacturer: Safetec of America, Inc.
887 Kensington Avenue
Buffalo, NY 14215

Company Telephone: 1-716-895-1822

E-mail Address: www.safetec.com

Emergency Telephone: 1-800-255-3924

Supplier Refer to Manufacturer

2. Hazard(s) identification

Physical hazards This mixture does not meet the classification criteria according to OSHA HazCom 2012.

Health hazards This mixture does not meet the classification criteria according to OSHA HazCom 2012.

Environmental hazards This mixture does not meet the classification criteria according to OSHA HazCom 2012.

OSHA defined hazards This mixture does not meet the classification criteria according to OSHA HazCom 2012.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention None required according to OSHA Hazcom 2012.

Response None required according to OSHA Hazcom 2012.

Storage None required according to OSHA Hazcom 2012.

Disposal None required according to OSHA Hazcom 2012.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Superabsorbent Polymer		9033-79-8	> 97
Sodium dichloro-s-triazinetrione	SODIUM DICHLOROISOCYANURATE	2893-78-9	0.25

4. First-aid measures

Inhalation If symptoms develop move victim to fresh air. Get medical attention if symptoms persist.

Skin contact Wash off with warm water and soap. Get medical attention if symptoms occur.

Eye contact Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Ingestion Seek medical advice.

Most important symptoms/effects, acute and delayed May be mildly irritating to skin, eyes and respiratory system.

Indication of immediate medical attention and special treatment needed	Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media	Water. Water Spray or Fog. Dry chemicals. Foam. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	Thermal decomposition or combustion may liberate toxic gases or fumes.
Special protective equipment and precautions for firefighters	None known.
Fire fighting equipment/instructions	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
General fire hazards	No unusual fire or explosion hazards noted.
Hazardous combustion products	Carbon oxides. Nitrogen oxides (NOx).

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid dust formation. Sweep up or vacuum up spillage and collect in suitable container for disposal. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. After dust removal, flush contaminated area thoroughly with water.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Avoid dust formation. Use only with adequate ventilation. Wash thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed. Keep cool. Store away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Chemical resistant gloves recommended.
Other	Wear chemical-resistant gloves, footwear, and protective clothing appropriate for the risk of exposure. Contact health or safety professional or manufacturer for specific information.
Respiratory protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Not available.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Granular powder.
Physical state	Solid.
Form	Powder.
Color	Off-white.
Odor	Slight chlorine.

Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slight.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	High humidity. High temperatures.
Incompatible materials	Strong reducing agents.
Hazardous decomposition products	Carbon oxides. Nitrogen oxides (NOx).

11. Toxicological information

Information on likely routes of exposure

Inhalation	Inhalation of dusts may cause respiratory irritation.
Skin contact	May cause mild skin irritation.
Eye contact	May cause mild eye irritation.
Ingestion	No harmful effects expected in amounts likely to be ingested by accident.
Most important symptoms/effects, acute and delayed	May be mildly irritating to skin, eyes and respiratory system.

Information on toxicological effects

Acute toxicity	No adverse effects are expected.
Skin corrosion/irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	May cause mild eye irritation.

Respiratory or skin sensitization

Respiratory sensitization	This product is not expected to cause respiratory sensitization.
Skin sensitizer	This product is not expected to cause skin sensitization.

Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	This product is not expected to cause reproductive effects.
Specific target organ toxicity - single exposure	Not classified as a specific target organ toxicity -single exposure.
Specific target organ toxicity - repeated exposure	Not classified as a specific target organ toxicity -repeated exposure.
Aspiration toxicity	Not expected to be an aspiration hazard.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	Not available.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

15. Regulatory information

US federal regulations	This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. All components are on the U.S. EPA TSCA Inventory List.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 02-23-2015

Version # 01

Disclaimer

Prepared by: ICC The Compliance Center Inc. 1-888-442-9628
http://www.thecompliancecenter.com

Disclaimer
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This Safety Data Sheet may not be changed, or altered in any way without the expressed knowledge and permission of ICC The Compliance Center Inc. and

Revision Information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Regulatory Information: United States
GHS: Classification

Bibliography

ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices (2014)
Canadian Centre for Occupational Health and Safety, CCInfoWeb Databases, 2014 (Chempendium, RTECs, HSDB, INCHEM)
European Chemicals Bureau, Existing Chemicals Work Area, EINECS Information System, 2014.
Material Safety Data Sheet from manufacturer.
OECD - The Global Portal to Information on Chemical Substances - eChemPortal, 2014.

SAFETY DATA SHEET

Creation Date 10-Nov-2014 **Revision Date** 10-Nov-2014 **Revision Number** 1

1. Identification

Product Name **Resolve Immersion Oil - Low Viscosity**

Cat No. : **M2000, M3000, M4000, M5000**

Synonyms No information available

Recommended Use Laboratory chemicals.

Uses advised against No Information available

Details of the supplier of the safety data sheet

Company
Richard Allan Scientific
A Subsidiary of Thermo Fisher Scientific
4481 Campus Drive
Kalamazoo, MI 49008
Tel: (800) 522-7270

Emergency Telephone Number
Chemtrec US: (800) 424-9300
Chemtrec EU: 001 (202) 483-7616

2. Hazard(s) identification

Classification
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Specific target organ toxicity (single exposure) Target Organs - Respiratory system.	Category 3
Specific target organ toxicity - (repeated exposure) Target Organs - Liver, Kidney.	Category 2

Label Elements

Signal Word
Warning

Hazard Statements
May cause respiratory irritation
May cause damage to organs through prolonged or repeated exposure

Precautionary Statements
Prevention
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Response
Get medical attention/advice if you feel unwell
Inhalation
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
Call a POISON CENTER or doctor/physician if you feel unwell
Storage
Store in a well-ventilated place. Keep container tightly closed
Store locked up
Disposal
Dispose of contents/container to an approved waste disposal plant
Hazards not otherwise classified (HNOC)
None identified

3. Composition / information on ingredients

Component	CAS-No	Weight %
White mineral oil	8042-47-5	52 - 55
Terphenyls	26140-60-3	1 - 4
Polyphenyls, quater- and higher, partially hydrogenated	68956-74-1	3 - 6
Polybutene	9003-29-6	7 - 10
Hydrogenated terphenyls	61788-32-7	27 - 33

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes.

Inhalation Move to fresh air.

Ingestion Do not induce vomiting.

Most important symptoms/effects No information available.
Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray. Dry chemical. Carbon dioxide (CO_2). alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point 148.89 °C / 300 °F

Method - No information available

Autoignition Temperature No information available
Explosion Limits
Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical
Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products
Carbon monoxide (CO) Carbon dioxide (CO_2)
Protective Equipment and Precautions for Firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health	Flammability	Instability	Physical hazards
2	1	0	-

6. Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment.
Environmental Precautions See Section 12 for additional ecological information.

Methods for Containment and Clean Up Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

7. Handling and storage

Handling Ensure adequate ventilation.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls / personal protection

Exposure Guidelines

Component	ACGIH TLV	OSHA PEL	NIOSH IDLH
Terphenyls	Ceiling: 5 mg/m³	Ceiling: 1 ppm Ceiling: 9 mg/m³ (Vacated) Ceiling: 0.5 ppm (Vacated) Ceiling: 5 mg/m³	IDLH: 500 mg/m³
Hydrogenated terphenyls	TWA: 0.5 ppm	(Vacated) TWA: 0.5 ppm (Vacated) TWA: 5 mg/m³	TWA: 0.5 ppm TWA: 5 mg/m³

Component	Quebec	Mexico OEL (TWA)	Ontario TWAEV
Terphenyls	Ceiling: 0.53 ppm Ceiling: 5 mg/m³	Ceiling: 0.5 ppm	CEV: 5 mg/m³
Hydrogenated terphenyls	TWA: 0.5 ppm TWA: 4.9 mg/m³	TWA: 0.5 ppm TWA: 5 mg/m³	TWA: 0.5 ppm

Legend

ACGIH - American Conference of Governmental Industrial Hygienists
OSHA - Occupational Safety and Health Administration
NIOSH IDLH: The National Institute for Occupational Safety and Health Immediately Dangerous to Life or Health

Engineering Measures Ensure adequate ventilation, especially in confined areas.
Personal Protective Equipment
Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.
Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.
Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State Liquid

Appearance	Light yellow
Odor	Odorless
Odor Threshold	No information available
pH	No information available
Melting Point/Range	No data available
Boiling Point/Range	No information available
Flash Point	148.89 °C / 300 °F
Evaporation Rate	No information available
Flammability (solid,gas)	No information available
Flammability or explosive limits	
Upper	No data available
Lower	No data available
Vapor Pressure	No information available
Vapor Density	No information available
Relative Density	0.92
Solubility	No information available
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	No information available

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products. Excess heat.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO_2)

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Oral LD50 Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg.
Dermal LD50 Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg.
Vapor LC50 Based on ATE data, the classification criteria are not met. ATE > 20 mg/l.

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
White mineral oil	>5000 mg/kg (Rat)	>3000 mg/kg (Rabbit)	Not listed
Terphenyls	Not listed	12500 mg/kg (Rabbit)	Not listed
Hydrogenated terphenyls	10200 mg/kg (Rat)	6800 mg/kg (Rabbit)	4.3 mg/L (Rat) 4 h

Toxicologically Synergistic Products No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
White mineral oil	8042-47-5	Not listed	Not listed	Not listed	Not listed	Not listed

Terphenyls	26140-60-3	Not listed	Not listed	Not listed	Not listed	Not listed
Polyphenyls, quater- and higher, partially hydrogenated	68956-74-1	Not listed	Not listed	Not listed	Not listed	Not listed
Polybutene	9003-29-6	Not listed	Not listed	Not listed	Not listed	Not listed
Hydrogenated terphenyls	61788-32-7	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental Effects No information available.

Teratogenicity No information available.

STOT - single exposure Respiratory system
STOT - repeated exposure Liver Kidney

Aspiration hazard No information available

Symptoms / effects,both acute and delayed No information available

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

.

Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea
White mineral oil	Not listed	10000 mg/L LC50 96 h	Not listed	Not listed
Terphenyls	0.02 mg/L EC50 = 96 h	0.11 mg/L LC50 96 h	Not listed	0.11 mg/L EC50 > 48 h
Hydrogenated terphenyls	0.53 mg/L EC50 > 96 h	0.53 mg/L LC50 96 h	Not listed	0.011 mg/L EC50 = 48 h

Persistence and Degradability No information available

Bioaccumulation/ Accumulation No information available.

Mobility .

Component	log Pow
White mineral oil	6

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT Not regulated
TDG Not regulated
IATA Not regulated
IMDG/IMO Not regulated

15. Regulatory information

All of the components in the product are on the following Inventory lists: Australia X = listed China Canada The product is classified and labeled according to EC directives or corresponding national laws The product is classified and labeled in accordance with Directive 1999/45/EC Europe TSCA Philippines

International Inventories

Component	TSCA	DSL	NDSL	EINECS	ELINCS	NLP	PICCS	ENCS	AICS	IECSC	KECL
White mineral oil	X	X	-	232-455-8	-		X	X	X	X	X
Terphenyls	X	X	-	247-477-3	-		X	X	X	X	X
Polyphenyls, quater- and higher, partially hydrogenated	X	X	-	273-316-1	-		X	-	X	X	-
Polybutene	X	X	-	-	-	products derived from But-1-ene or But-2-ene, consisting of 50% w/w or more of species of the same molecular weight	X	X	X	X	X
Hydrogenated terphenyls	X	X	-	262-967-7	-		X	X	X	X	X

Legend:
X - Listed
E - Indicates a substance that is the subject of a Section 5(e) Consent order under TSCA.
F - Indicates a substance that is the subject of a Section 5(f) Rule under TSCA.
N - Indicates a polymeric substance containing no free-radical initiator in its inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.
P - Indicates a commenced PMN substance
R - Indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
S - Indicates a substance that is identified in a proposed or final Significant New Use Rule
T - Indicates a substance that is the subject of a Section 4 test rule under TSCA.
XU - Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(B).
Y1 - Indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.
Y2 - Indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

U.S. Federal Regulations

TSCA 12(b) Not applicable

SARA 313 Not applicable

SARA 311/312 Hazardous Categorization

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act Not applicable

Clean Air Act Not applicable

OSHA Occupational Safety and Health Administration
Not applicable

CERCLA
Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals

State Right-to-Know

Component	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Terphenyls	X	X	X	-	X
Hydrogenated terphenyls	X	X	X	-	-

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland Security
This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade Slight risk, Grade 1

Canada
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR

WHMIS Hazard Class D2B Toxic materials

16. Other information

Prepared By Regulatory Affairs
Richard Allan Scientific
A Subsidiary of Thermo Fisher Scientific
Tel: (800) 522-7270

Creation Date 10-Nov-2014
Revision Date 10-Nov-2014
Print Date 10-Nov-2014
Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard replacing the current legislation under 29 CFR 1910.1200 to align with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Disclaimer
The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of SDS

Reztore® Surface & Mat Cleaner Application Instructions

Made in the United States of America

Figure 1. Reztore® Surface & Mat Cleaner:
16 Ounces (500 mL) Spray Bottle
1 Quart (1 liter) Spray Bottle
2.5 Gallons (10 liters) Bag-in-Box

Description

Reztore® Surface & Mat Cleaner is a liquid cleaner used to remove dust, grease, grime, fingerprints, and solder flux from all surfaces used in a static sensitive area. Reztore® Surface & Mat Cleaner leaves no insulative residue, contains no alkali or ammonia, and according to NFPA and OSHA, is "non-flammable".

General Guidelines

Reztore® Surface & Mat Cleaner is a liquid cleaner which can be used on a variety of surfaces, especially surfaces used in a static sensitive environment. Surfaces include but are not limited to: rubber, vinyl and polyethylene table and floor mats, field service kits, laminated table tops, tote boxes, epoxy, painted surfaces, plexiglass, glass, metal, 3-ring binders, computer screens, computer keyboards, shelving, push carts, conveyor belts, etc.

NOTE: Cleaners with silicone leave an insulative residue on surfaces and solvents such as 2-Butoxyethanol or Ethanolamine used in cleaners can dry out the material; both can prevent conductive or dissipative mats from functioning properly.

“Periodic cleaning, following the manufacturer’s recommendations, is required to maintain proper electrical function on all work surfaces. Ensure that cleaners that are used do not leave an electrically insulative residue common with some household cleaners that contain silicone.” (ESD Handbook ESD TR20.20 section 5.3.1.14 Worksurface Maintenance)

“Only cleaning materials or processes which do not degrade the properties of the ESD protective items, shall be used.” (EN 61340-5-1 clause 5.5 EPA working practices)

Directions

Smooth Surfaces:

Apply Reztore® Surface & Mat Cleaner to the entire surface to be treated using either the pump or trigger spray bottle. Use a lint-free cloth to wipe the surface until dry. For set stains, let Reztore® Surface & Mat Cleaner soak on the surface for 30 seconds before wiping clean.

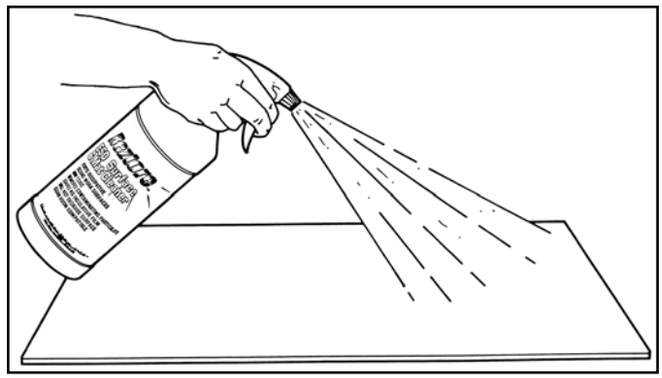

Figure 2. Applying Reztore® to the mat

Other Surfaces - Keyboards:

Dampen a lint-free cloth or a lint-free swab with Reztore® Surface & Mat Cleaner. Wipe surface to be cleaned using either the cloth or swab. The swab will work best for tight spots like between keyboard keys. Use the cloth to wipe clean the remaining surfaces of the keyboard.

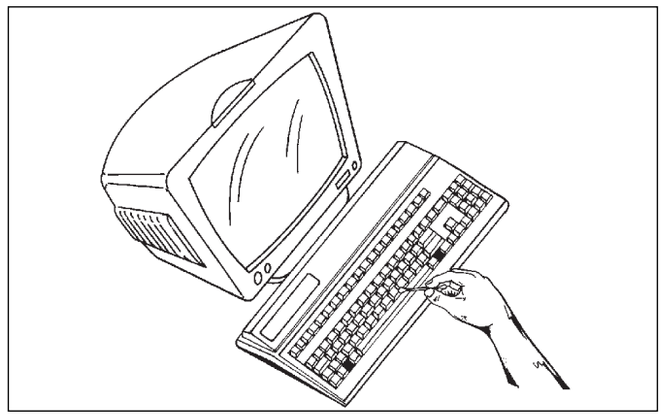

Figure 3. Cleaning a keyboard or computer screen with Reztore® Surface & Mat Cleaner

On non-ESD surfaces, we recommend using Reztore® Topical Antistat static dissipative coating. While coating is on the surface it will enhance existing ESD surfaces and will give dissipative electrical properties to insulative surfaces.

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Specifications

Appearance of Solution	Transparent violet
pH	6.0 - 8.0
Odor	Slight floral
Solubility	Water, acetone, alcohols
Toxicity, Irritation, Sensitivity	Non-toxic by dermal contact, or inhalation
Flammability	"Non-flammable" per NFPA and OSHA. Flammable Cat. 3 per CLP
Ion Level (mg/L)	Fluoride 0.3 Sulfate <0.5 Nitrate 1.2 Bromide <0.5 Phosphate <0.5
Electrical Properties (Dry Film)	1×10^7 to $< 1 \times 10^9$ ohms (ref. ANSI/ESD S4.1)
Static Decay Rate	<0.01 seconds (per FTMS 101C Method 4046)

Testing

It is recommended to test the surface after cleaning to ensure that all insulative contaminants such as dirt and grime have been removed. Reztore® Surface & Mat Cleaner will only leave behind a coating with a surface resistance of less than 1×10^9 ohms.

Storage

Reztore® Surface & Mat Cleaner product does not have a set life span. The chemicals are not known to degrade over time when stored at the proper temperature conditions as stated in the Safety Data Sheet. We also recommend that this product be stored in its original container and be sealed when not in use.

RoHS 3, REACH, and Conflict Minerals Statement
See the Desco Industries RoHS 3, REACH, and Conflict Minerals Statement:
DescoIndustries.com/ROHS.aspx

Desco Industries Limited Warranty
See the Desco Industries Limited Warranty:
DescoIndustries.com/Warranty.aspx

Reztore® Surface and Mat Cleaner is available from these Desco Industries brands:

DESCO

for service and support in North America

16 Oz.	10439
1 Quart	10435
2.5 Gallons	10438

DESCO EUROPE

for service and support in United Kingdom and Europe

1 Litre	229021
1 Litre 12 Packs	229022
10 Litres	229023

DESCO ASIA

for service and support in Asia

0.5 Liter	10439
1 Liter	10435
10 Liters	10438

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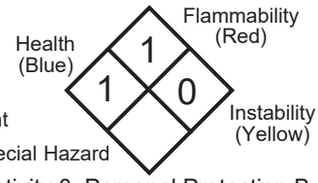
Safety Data Sheet
May be used to comply with ANSI Z400.1-2004, 29 CFR 1910.1200, Regulation (EC) No 1272/2008 (CLP Regulation) and GHS. Standards must be consulted for specific requirements.

Revision Date: 2017-11-16

NFPA Designation 704

Degree of Hazard
4 = Extreme
3 = High
2 = Moderate
1 = Slight
0 = Insignificant



HMIS RATING: Health 1, Flammability 1, Reactivity 0, Personal Protection B

SECTION 1 — IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product Name:	Reztore® Surface and Mat Cleaner
EC No.:	None
REACH Registration No.:	None
CAS No.:	None

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: Cleaner, ESD Surface & Mat

1.3 Details of the supplier of the safety data sheet

Supplier: Desco Industries, Inc.

United States
One Colgate Way
Canton, MA 02021
781-821-8370

United Kingdom
2A Dunhams Lane
Letchworth Garden City
Hertfordshire, SG6 1BE
01462 672005

Japan
661-1 Yachimata-ho
Yachimata-Shi
Chiba-Ken 289-1115
+81 43-309-4470

Email Address: Service@DescoIndustries.com

1.4 Emergency telephone number

Emergency Number: 781-821-8370

SECTION 2 — HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Flammable liquid	Category 3
Eye irritation	Category 2
Specific target organ toxicity (Single exposure)	Category 3

2.2 Label elements

Symbol: Flame, Exclamation mark.

Signal word: Warning.

Hazard statement:
(H226): Flammable liquid and vapor.
(H319): Causes serious eye irritation.
(H336): May cause drowsiness or dizziness.

Precautionary statements:
(P210): Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
(P240): Ground/bond container and receiving equipment.
(P241): Use explosion-proof electrical/vetilating/lighting equipment.
(P242): Use only non-sparking tools.
(P261): Avoid breathing dust/fume/gas/mist/vapours/spray.
(P264): Wash hands thoroughly after handling.
(P271): Use only outdoors or in a well-ventilated area.
(P280): Wear protective gloves/protective clothing/eye protection/face protection.
(P303+P361+P353): IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
(P304+P340+P312): IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

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	(P305+P351+P338): IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P337+P313): If eye irritation persists: Get medical advice/attention. (P403+P235): Store in a well-ventilated place. Keep cool. (P233): Keep container tightly closed. (P405): Store locked up. (P501): Dispose of contents/container in compliance with all Federal, National and Local laws and regulations.
2.3 Other hazards	N/A

SECTION 3 — COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances N/A

3.2 Mixtures

Hazardous Ingredients	CAS No.	Weight %
Isopropanol	67-63-0	5 - 25 %

SECTION 4 — FIRST AID MEASURES

4.1 Description of first aid measures

Eye Contact	Flush with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Skin Contact	Wash with soap and water. If skin irritation occurs: Get medical advice/attention.
Ingestion	Drink several glasses of water. DO NOT induce vomiting. Contact a physician.
Inhalation	Move subject to fresh air.

4.2 Most important symptoms and effects, both acute and delayed

N/A

4.3 Indication of any immediate medical attention and special treatment needed

N/A

SECTION 5 — FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media	Water
Unsuitable Extinguishing Methods	N/A

5.2 Special hazards arising from the substance or mixture N/A

5.3 Advice for firefighters

In the event of fire wear self-contained breathing apparatus.
Cool containers with water.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wearing protective clothing. Inhalation protection. Extinguish all ignition sources.

6.2 Environmental precautions

Biodegradable.

6.3 Methods and materials for containment and cleaning up

Contain and collect material into plastic container. Water rinse and drain, flush small amounts. Use sanitary landfill disposal. Follow national and local regulations (RCRA; Subtitle D).
If Material is Released/Spilled: Keep spectators away. Contain spill with inert material (e.g. sand, earth). Keep spills and cleaning runoffs out of municipal sewers and open bodies of water.

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6.4 Reference to other sections

See SECTION 13, Disposal Considerations, for information regarding the disposal of contained spills.

SECTION 7 — HANDLING AND STORAGE

7.1 Precautions for safe handling

Use in well-ventilated areas; avoid breathing vapors. Keep containers closed when not in use. Avoid from freezing.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry place with adequate ventilation. Keep from freezing - product may coagulate.
Storage temperature: Max. 49°C/120°F 1°C/34°F

7.3 Specific end uses N/A

SECTION 8 — EXPOSURE CONTROL / PERSONAL PROTECTION

8.1 Control parameters

TLV-value 400 ppm maximum for Isopropanol.

Hazardous Ingredients	CAS No.	TLV-value
Isopropanol*	67-63-0	400 ppm

8.2 Exposure controls

Technical Control Measures	Preferences of technical measure to prevent or control contact with the product. Isolating process and personnel, mechanical ventilation (dilution and local exhaust) and the regulation of process conditions. In case of non-prevention or non-control, a proper protective wearing should be used.
Hygiene Measures	Wash hands before eating, smoking, or using washroom facilities

Individual protection measures

Eye/Face Protection	Safety glasses or Chemical splash goggles as defined in ANSI Z-87.1 or a similar standard.
Skin Protection	No precautions other than clean body covering clothing should be needed.
Hand Protection	Impervious/Neoprene Gloves.
Respiratory Protection	Wear MSHA/NIOSH approved respirator where exposure limits are exceeded.
Ingestion	Use good personal hygiene. Do not consume or store food in the work area. Wash hands before smoking or eating.

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Liquid.
Color:	Clear violet.
Odor:	Floral Alcohol.
Odor Threshold:	N/A.
pH:	6.0 - 8.0
Melting Point:	N/A.
Boiling Point:	>200°F (93.3°C)
Flash Point:	106°F (41°C)
Evaporation rate:	0.28
Flammability:	Classification according to NFPA and OSHA as “non-flammable”. Flammable Category 3 according to EU and GHS.
Upper flammability or explosive limits:	N/A
Lower flammability or explosive limits:	N/A
Vapor Pressure (mm Hg):	18.0
Vapor Density (air=1):	1.06
Relative Density:	8.17 lbs./gal at 20°C
Specific Gravity (H_2O = 1) :	0.98
Solubility:	Completely
Partition coefficient:	N/A

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Auto-ignition temperature:	N/A
Decomposition temperature:	N/A
Viscosity:	N/A
Explosive properties:	N/A
Oxidizing properties:	N/A

9.2 Other information

VOC per Method 24 of EPA: 1% VOC by wt.

SECTION 10 — STABILITY AND REACTIVITY

10.1 Reactivity N/A

10.2 Chemical stability
Stable product at normal conditions.

10.3 Possibility of hazardous reactions N/A

10.4 Conditions to avoid
Temperatures above 100°F (38°C) and below 34°F (1°C)

10.5 Incompatible materials
Strong Oxidizers.

10.6 Hazardous decomposition products
Thermal decomposition may yield carbon monoxide.

SECTION 11 — TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

All information refers to the main component Isopropanol

Acute toxicity:	None known.
Special Effects:	None known.

SECTION 12 — ECOLOGICAL INFORMATION

12.1 Toxicity N/A

12.2 Persistence and degradability N/A

12.3 Bioaccumulative potential
Not likely.

12.4 Mobility in soil
The product is aqueous and will be separated in aqueous conditions.

12.5 Results of PBT and vPvB assessment N/A

12.6 Other adverse effects N/A

12.7 Additional Information
No environmental hazards have been reported or known.

SECTION 13 — DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Contain and collect material into plastic container. Water rinse and drain, flush small amounts. Use sanitary landfill disposal. Follow state and local regulations (RCRA; Subtitle D).

13.2 Additional information N/A

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SECTION 14 — TRANSPORT INFORMATION

This product is not classified for transport under ADR/IMDG regulations.

This product is not classified as a flammable liquid according to DOT and IATA transportation standards and is not regulated as such.

14.1 UN Number	N/A
14.2 UN proper shipping name	N/A
14.3 Transport hazard class(es)	N/A
14.4 Packing group	N/A
14.5 Environmental hazards	N/A
14.6 Special precautions for user	N/A
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code	N/A

SECTION 15 — REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Physical/Chemical Indication	Non-flammable (NFPA and OSHA), Flammable (EU and GHS)

***These items are listed and subjected to the reporting requirements of the SARA Title III Section 313 Inventory of the Emergency Planning and Community Right-To-Know Act of 1986 and of 40 CFR37.**

CAS Number: 67-63-0 with maximum weight 25%

EINECS Status	All components are included in the EINECS Inventories.
TSCA	All ingredients of this product are listed or are excluded from the listing on the U.S. Toxic substance.
REACH	This product does not required REACH registration.
15.2 Chemical Safety Assessment	N/A

SECTION 16 — OTHER INFORMATION

HMIS RATING	Health 1, Flammability 1, Reactivity 0, Personal Protection B
NFPA RATING	Special Hazard: N/A, Health: 1, Flammability: 1, Instability: 0
SDS Updated	**2017-11-16**

Disclaimer

OTHER INFORMATION: This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to the best of the company's knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy, reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of use. It is the user's responsibility to satisfy himself as to the suitableness and completeness of such information for his own particular use.

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BECKMAN COULTER
RF Calibrator

SAFETY DATA SHEET

Document ID: ODC0028-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name RF Calibrator

Part Number ODC0028

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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BECKMAN COULTER
RF Calibrator

SAFETY DATA SHEET

Document ID: ODC0028-75 Version 05
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	≈ 1 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 4, 6, 8, 10 - 12, 14 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/07/03
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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR61105-75: Version 05
Revision Date (year/month/day) 2020/05/14
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Product Information

Product Name	RF Latex
Part Number	OSR61105

Components

Description	RF Latex R1 RF Latex R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name RF Latex R1

Part Number Component of P/N OSR61105

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless to slightly yellow; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

2-Methyl-4-isothiazolin-3-one

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.
H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.5.6% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

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Section 3 Composition and Information on Ingredients (Continued)

Citric Acid CAS # 77-92-9 EINECS # 201-069-1 Index # Not available	1 - 2	Eye Irrit. 2, H319	Eye Irrit. 2, H319	3, 8
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available	< 0.06	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=10 M-factor Chronic=1 Skin Corr. 1B, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 Skin Sens. 1A, H317	

2 - Substance with Community workplace exposure limits
3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

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Section 5 Fire Fighting Measures (Continued)

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Citric Acid CAS # 77-92-9	4 mg/m3 Peak (respirable fraction); 2 mg/m3 TWA MAK (inhalable fraction)
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4	0.4 mg/m3 Peak (mixture in ratio 1:3 with CAS 26172-55-4) (inhalable fraction); 0.2 mg/m3 TWA MAK (mixture in ratio 1:3 with CAS 26172-55-4) (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01576 @20°C

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Section 9 Physical and Chemical Properties (Continued)

	Color	Colorless to slightly yellow	**Solubility**	
	Transparency	Clear	**Water**	Miscible
	Odor	Odorless	**Organic**	Not determined
	pH	8	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
	Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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SAFETY DATA SHEET
Document ID: OSR61105-75 Version 05
Revision Date (year/month/day) 2020/05/14
Last Revision Date (year/month/day) 2015/03/20

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Citric Acid CAS # 77-92-9	Dermal LD50 Rat >2000 mg/kg (no deaths occurred); Oral LD50 Rat 3 g/kg
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4	Dermal LD50 Rabbit 200 mg/kg; Inhalation LC50 Rat 0.11 mg/L 4 h; Oral LD50 Rat 232 - 249 mg/kg (50% MIT in water); Oral LD50 Rat 120 mg/kg (50% MIT in water)

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Citric Acid CAS # 77-92-9	96 h LC50 Lepomis macrochirus: 1516 mg/L

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Update of product hazard and label elements in Sec. 2.
Updated hazardous ingredients in Section 3.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Revised Beckman Coulter safety rating.
Updated Section 4, 6, 8, 11, 12, 14 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/05/14
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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1

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Section 16 Other Information (Continued)

Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1A - Skin Sensitization Category 1A
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name RF Latex R2

Part Number Component of P/N OSR61105

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

White; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain ef , store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	White	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.3	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 4, 6, 8, 11, 12, 14 - 16.

Document version and issue/revision date

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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Section 1 – Product & Company Identification

Product Name:	RPMI Medium 1640
Product Number:	9160
Company:	Irvine Scientific 2511 Daimler Street Santa Ana, California 92705 USA
Technical Phone Number:	800-437-5706
Fax Number:	949-261-6522
Emergency Phone Number:	800-437-5706
E-Mail Address:	tmrequest@irvinesci.com

Section 2 – Hazards Identification

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS].

Section 3 – Composition/Information on Ingredients

Product name	CAS Number	EC Number	Annex I Number
RPMI Medium 1640	None	None	None

Section 4 – First Aid Measures

General information:	When in doubt or if symptoms are observed, get medical advice.
In case of inhalation:	Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration.
In case of skin contact:	Wash immediately with soap and water. In case of skin irritation, consult a physician.
In case of eye contact:	Rinse immediately carefully and thoroughly with eye-bath or water.
In case of ingestion:	Rinse mouth thoroughly with water.

Section 5 – Fire Fighting Measures

Suitable Extinguishing Media: Water, foam, extinguishing powder, carbon dioxide (CO_2)
Extinguishing media which must not be used for safety reasons: None
In case of fire may be liberated: Emits toxic fumes under fire conditions
Special protective equipment for fire-fighters: Wear a self-contained breathing apparatus

Section 6 – Accidental Release Measures

Personal precautions: Provide adequate ventilation
Environmental Precautions: None
Methods for cleaning up:
Suitable material for diluting or neutralizing: water
Suitable material for taking up: sand, absorbing material, earth

Section 7: Handling & Storage

Handling: Avoid inhalation. Avoid skin contact. Avoid eye contact.
Storage:
Storage temperature: 2-8^{o}C
Protect against: Light
Conditions: Keep tightly closed

Section 8 – Exposure controls / Personal protection

Exposure limit values: Not available

Exposure Controls:
Product related measures to prevent exposure: Observe the expiry date
Personal protection equipment:
Respiratory protection: No personal respiratory protective equipment normally required. Where protection is desired, use multi-purpose combination (US) or type ABEK (EN14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Hand protection: disposable gloves
Eye protection: Eye glasses
Protective clothing: Lab coat
General health and safety measures: Avoid contact with skin, eye and clothing. Remove contaminated, saturated clothing. Wash contaminated clothing prior to re-use.

Section 9 – Physical and Chemical Properties

General:
Physical State: Liquid
Color: Clear red solution
Odor: Characteristic

Important health, safety and environmental information:
pH value: Neutral
Melting point / melting range: Not available
Solidifying point: Not available
Freezing point: Not available
Boiling point: Not available

Vapor pressure: Not available
Density: Not available
Bulk density: Not available
Solubility: Water
Viscosity: Not available
Flow time: Not available

Other information:
Solvent Content (%): 0%

Section 10 – Stability and Reactivity

Stability: Stable
Conditions to avoid: Temperatures below 0^{o}C
Materials to avoid: Oxidizing agents, Strong; Reducing agent, strong
Hazardous decomposition products: Unknown

Section 11 – Toxicological Information

Toxicokinetics metabolism and distribution: Not determined
Toxicological effects: Not determined
Irritant and corrosive effects: May cause irritation to skin, eyes, or mucous membranes.

Section 12 – Ecological Information

Ecotoxicity: Not determined
Mobility: Not determined
Persistence and degradability: Not available
Biodegradation: Evidence exists of biodegradation processes
Bioaccumulative potential: Does not significantly accumulate in organisms.
Overall evaluation: On the basis of existing data about the elimination/degradation and bioaccumulation, potential longer term damage to the environment is unlikely.
BOD5 and COD: Not available

Section 13 – Disposal Considerations

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

Section 14 – Transportation Information

Land transport (ADR/RID): Not a dangerous good in sense of this transport regulation.
Inland water ways transport (ADN): Not a dangerous good in sense of this transport regulation.
Sea transport (IMDG): Not a dangerous good in sense of this transport regulation.
Air transport (ICAO-TP / IATA-DGR): Not a dangerous good in sense of this transport regulation.
DOT Classification: Not a DOT controlled material (United States)

Section 15 – Regulatory Information

For this mixture a chemical safety assessment has not been carried out.

Germany: WGK: 1 - Self-Assessment

Listed European Food Additive: None of the ingredients are on the inventory, and may be exempt from listing.
TSCA Inventory List: None of the ingredients are on the inventory list.
CERCLA: Not Available
SARA Title III: Not Available
Foreign Inventory List: Not Available

Section 16 – Other Information

HMIS Rating Health = 1 Fire = 0 Reactivity = 0

Irvine Scientific supplies Safety Data Sheets (SDS) for products you have purchased. The regulations promulgated by OSHA for Hazard Communication, 29 CFR 1910.1200, and 1907/2006/EC and are used as the basis for the development of the SDS.
All information is offered in good faith as accurate, but is furnished without guaranty. No claim is made that the information is all inclusive, and should only be used as a guide. Irvine Scientific shall not be held liable for any damage resulting from handling or from contact with the product. Federal and California Hazard Communication regulations stipulate that any food, food additive, color additive, drug, cosmetic or medical or veterinary device or product, including materials intended for use as ingredients in such products (e,g, flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq) or the Virus-Serum-Toxic Act of 1913 (21 USC 151 et seq,), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture do not require labeling.

SAFETY DATA SHEET

Revision Date: OCT 2016

Arlington Scientific, Inc.
Springville, UT 84664
www.arlingtonscientific.com

1. PRODUCT AND COMPANY IDENTIFICATION	
Product name:	**ASI Rapid Plasma Reagin (RPR) Card Test for Syphilis**
Product number:	900025 25 Test Kit 900100 100 Test Kit 900500 500 Test Kit 9005000-10 5000 Test Kit 9005000-30 5000 Test Kit 90010000 10000 Test Kit
Brand:	ASI
Company:	Arlington Scientific Inc. 1840 N Technology Drive Springville, UT 84663 USA
Telephone:	(801) 489-8911
Fax:	(801) 489-5552
Emergency phone #:	(801) 489-8911

2. HAZARDS IDENTIFICATION	
Emergency overview:	This product is not classified according to the Global Harmonized System (GHS).
OSHA hazards:	NFPA and HMIS ratings: Health = 2; Flammability = 0; Reactivity = 0
Flammable liquid:	None
Target organ effect:	None
Harmful by ingestion:	Avoid hand-to-mouth contact when handling human serum source materials. Wash hands thoroughly after handling, even when gloves have been worn. Do not eat, drink, or apply cosmetics in the area where human source material is handled. Do not pipet by mouth.
Harmful by skin absorption:	Wear gloves and especially cover any cuts, abrasions, or skin lesions. Dispose of gloves, pipets, stirrers, test cards, and used reagent containers as biohazardous material. Wash hands thoroughly after removing gloves. Use extreme caution with any sharp object to avoid percutaneous exposure to human source material. Wear outer protective garment such as a lab coat or gown.
Irritant:	None
Target organs:	None
Potential health effects:	
Inhalation:	No irritating effect.
Skin:	No irritating effect.
Eyes:	No irritating effect.
Ingestion:	No irritating effect.

3. COMPOSITION/INFORMATION ON INGREDIENTS	
Formula:	Reagents contained in kit: 1. RPR Carbon Antigen - Containing: 0.003% cardiolipin, 0.020 - 0.022% lecithin, 0.09% cholesterol, activated charcoal as a visual enhancer, phosphate buffer, stabilizers, and 0.1% sodium azide as a preservative. There is no hazardous ingredient in concentration greater than 1%. 2. Reactive, Weak Reactive, and Nonreactive control reagents: ASI controls contain human serum or defibrinated plasma with 0.1% sodium azide as a preservative. All compounds derived from human source materials have been tested at the donor level and found to be nonreactive for HBsAg and for HIV-1, HIV-2, and HCV antibodies. Because no known test offers complete assurance that infectious agents are absent, all materials derived from human blood should be handled as if capable of transmitting infection.

4. FIRST AID MEASURES	
General Advice:	Symptoms of mild discomfort may be exhibited after several hours; therefore observe for any medical

SAFETY DATA SHEET

Revision Date: OCT 2016

Arlington Scientific, Inc.
Springville, UT 84664
www.arlingtonscientific.com

	symptoms for at least 48 hours.
If inhaled:	Remove from source to fresh air. If breathing becomes difficult, call a physician.
In case of skin contact:	Wash thoroughly with soap and water. Remove contaminated clothing. Call a physician.
In case of eye contact:	Flush with large amounts of water or sterile eye wash. Use fingers to separate the eyelids for effective flushing. Call a physician.
If swallowed:	If conscious, wash out mouth with water. Call a physician.

5. FIRE-FIGHTING MEASURES	
Flammable properties:	None
Suitable extinguishing media:	CO2, or multiple dry chemical or water spray.
Special protective equipment: for Fire-Fighters	No special measures required.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions:	Personal precautions, protective equipment, and emergency procedures are not required.
Environmental precautions:	Not a risk to environment.
Methods for cleaning up:	Clean-up with water moistened cloth or mop. After material has been cleaned-up and removed, wash the spilled area site with a disinfectant cleaner.

7. HANDLING AND STORAGE	
Handling	Ensure adequate ventilation and fresh air supply in HVAC
Storage	Store at 2 – 8°C, and avoid freezing

8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
Personal precautions	
Respiratory protection	None required
Hand protection	Surgical gloves
Eye protection	Standard laboratory eye ware
Skin and body protection	Typical laboratory coat or gown
Hygiene measures	No special measures required
Personal precautions	No special precautions required
Respiratory protection	Wear surgical mask if indicated by local procedures

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance	
Form	Liquid
Color	Control reagents are transparent; carbon antigen exhibits suspended black particles
Odor	None
Safety data	ASI Reagents contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large amounts of water to prevent azide build-up.

10. STABILITY AND REACTIVITY	
Storage stability	Refrigerate at 2 – 8°C
Conditions to avoid	Avoid temperatures outside the range of 2 – 8°C. Avoid freezing.
Materials to avoid	None
Hazardous decomposition products	None
Hazardous reactions	None

11. TOXICOLOGICAL INFORMATION	
Potential health effects	None

SAFETY DATA SHEET

Revision Date: OCT 2016

Arlington Scientific, Inc.
Springville, UT 84664
www.arlingtonscientific.com

Inhalation	Not an irritant.
Skin	Not an irritant
Eyes	Not an irritant
Ingestion	Not an irritant
Target organs	None

12. ECOLOGICAL INFORMATION

Elimination information	No ecological effects currently identified.

13. DISPOSAL CONSIDERATIONS

Product	ASI reagents contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large amounts of water to prevent azide build-up. Smaller quantities can be disposed of with solid waste. This product is not considered an RCRA hazardous waste. Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

14. TRANSPORTATION INFORMATION

DOT (US)	Non-hazardous.

15. REGULATORY INFORMATION

	FDA 510(k) K851504 (CDRH) FDA 510(k) BK130001 (CBER) FDA 510(k) K111356 (CDRH)
	CLIA, Moderately complex

16. OTHER

	To the best of our knowledge, the information provided in this Safety Data Sheet is accurate. ASI does not assume any liability for the accuracy of completeness of the information. Final suitability of a material is the responsibility of the user. All materials may present unknown hazards and should always be used with caution. Although hazards are described in this Safety Data Sheet, ASI does not guarantee that these issues are the only hazards that exist.

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 628026-75 Rev. AE
Revised (year/month/day) 2015/04/30

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Coulter® S-Cal™ Calibrator

Part Number 628026

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Red; Opaque; Suspension; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Suspension	**Specific Gravity (Water=1.0)**	1.045 @20°C
Color	Red	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.5 - 6.8	**Partition coefficient: n-octanol/water**	Not determined
Melting Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product.

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

5-Fluorouracil is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Tetracycline Hydrochloride is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Methanol is listed.

Sodium Phosphate, Dibasic is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

5-Fluorouracil has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Tetracycline Hydrochloride has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

5-Fluorouracil is listed.
Methanol is listed.
Glutaraldehyde is listed.
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

5-Fluorouracil is listed.
Tetracycline Hydrochloride is listed.
Methanol is listed.
Glutaraldehyde is listed.
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

Pennsylvania RTK

5-Fluorouracil is listed.
Methanol is listed.
Glutaraldehyde is listed.
Sodium Phosphate, Dibasic is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Methanol
Citric Acid
Glutaraldehyde
Iodoacetamide
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated hazardous ingredients in Section 3.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 *Reviewed on 09/18/2020*

1 Identification

· **Product identifier**

· **Trade name: D-100 Sample Diluent**

· **Catalog or product number:** 2901009, 12008595
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not Applicable
· **Hazard pictograms** Not Applicable
· **Signal word** Not Applicable
· **Hazard statements** Not Applicable

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Not applicable.
· **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Sample Diluent

(Contd. of page 1)

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Dilute with plenty of water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 *Reviewed on 09/18/2020*

Trade name: D-100 Sample Diluent

(Contd. of page 2)

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	7
· **Change in condition**	
Melting point/Melting range:	0 °C
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density at 20 °C:**	1.00005 g/cm³
· **Relative density**	Not determined.
· **Vapor density**	Not determined.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 *Reviewed on 09/18/2020*

Trade name: D-100 Sample Diluent

(Contd. of page 3)

· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic at 20 °C:	0.952 mPas
kinematic:	Not determined.
· **Solvent content:**	
Water:	100.0 %
Solids content:	0.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 Reviewed on 09/18/2020

Trade name: D-100 Sample Diluent

(Contd. of page 4)

· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **ADR**	Not Regulated
	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/18/2020 *Reviewed on 09/18/2020*

Trade name: D-100 Sample Diluent

(Contd. of page 5)

· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not Regulated

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
All components have the value ACTIVE.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

US

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Trade name: D-100 Sample Diluent

(Contd. of page 6)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 09/18/2020 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· *** Data compared to the previous version altered.**

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 467826-75 Rev. AJ
Revised (year/month/day) 2016/10/19

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Diluent 1

Part Number 467826

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements — **According to US-OSHA / UN GHS**

Hazardous Ingredients
Tris(hydroxymethyl)– aminomethane

Pictogram
None

Signal Word
WARNING

Hazard Statements
H316 Causes mild skin irritation.

Precautionary Statements
P332+P313 If skin irritation occurs: Get medical advice/attention.

Product label will display most significant precautionary statements.

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Xi;R36/37/38	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

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Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at Room Temperature, as directed on the Product Label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses — No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈1.003 @24°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	7.3 - 7.9	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation Causes mild skin irritation.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity – single exposure	
	Not classified based on available data.
Specific target organ toxicity – repeated exposure	
	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2 Additional information	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
CERCLA RG's, 40 CFR 302.4	No ingredients listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Benzyl Alcohol is listed.
New Jersey Dept. of Health RTK List	No ingredients listed.
Pennsylvania RTK	Benzyl Alcohol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 15 Regulatory Information (Continued)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Benzyl Alcohol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the storage temperature.
Updated section 4,8,11,13
Updated Section 7.
Updated Section 16.

Hazard Class, hazard statements and risk phrase description from section 3

Xi - Irritant
R36/37/38 Irritating to eyes, respiratory system and skin.
Eye Irrit. 2 - Eye Irritation Category 2
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods

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Section 16 Other Information (Continued)

IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 81908-75 Rev. AG
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name SAMPLE DILUENT A

Part Number 81908

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless to yellow; Clear; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated alkyl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.
H402 Harmful to aquatic life.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	No	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	Acute Tox. Oral 4 Aquatic Acute 1 Eye Dam. 1 H302; H318; H400	

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

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Section 5 Fire Fighting Measures (Continued)

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.04 @20°C
Color	Colorless to yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

1. Product and Company Identification

Product identifier **Sani-Cloth HB Germicidal Disposable Wipe** **SDS0042**

Other means of identification Not available

Recommended use Hard, Nonporous Surface Disinfectant

Recommended restrictions For Professional and Hospital Use

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Professional Disposables International, Inc.

Address Two Nice-Pak Park,
Orangeburg, NY 10962-1376

Telephone 1-845-365-1700 (M-F 9am - 5pm)

Emergency phone number 1-800-999-6423

2. Hazards Identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not determined.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information Not applicable.

3. Composition/Information on Ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Benzyl-C12-18-alkyldimethyl ammonium chlorides		68391-01-5	0.07
Quaternary ammonium compounds, C12-14-alkyl[(ethylphenyl)methyl]di methyl, chlorides		85409-23-0	0.07

4. First Aid Measures

Inhalation Not a normal route of exposure.

Skin contact If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Eye contact	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Ingestion	Do not induce vomiting. Never give anything by mouth if victim is unconscious, or is convulsing. Obtain medical attention.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Treat patient symptomatically.
General information	If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance. Avoid contact with eyes, skin and clothing. Keep out of reach of children.

5. Fire Fighting Measures

Suitable extinguishing media	Treat for surrounding material.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Firefighters should wear a self-contained breathing apparatus.
Special protective equipment and precautions for firefighters	Firefighters should wear full protective clothing including self contained breathing apparatus.
Fire-fighting equipment/instructions	In the event of fire, cool product with water spray.
Specific methods	Cool product exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Prevent entry into waterways, sewers or confined areas. Pick up and discard towel. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling	Use good industrial hygiene practices in handling this material. Do not reuse towelette. Do not reuse the empty container. When using do not eat or drink.
Conditions for safe storage, including any incompatibilities	Store in a closed container away from incompatible materials. Store away from incompatible materials (see Section 10 of the SDS). Keep out of reach of children.

8. Exposure Controls/Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	This material does not have established exposure limits.
Appropriate engineering controls	Ensure adequate ventilation.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear gear as deemed necessary. Follow label directions.
Skin protection	
Hand protection	Wear as deemed necessary, follow label directions.
Other	As required by employer code.
Respiratory protection	Where exposure guideline levels may be exceeded, use an approved NIOSH respirator.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. Washing with soap and water after use is recommended as good hygienic practice to prevent possible eye irritation from hand contact. When using do not eat or drink.

9. Physical and Chemical Properties

Appearance	Liquid saturated on wipe
Physical state	Solid.
Form	Liquid saturated on wipe
Color	White
Odor	Mild quat
Odor threshold	Not available.
pH	10.75 (liquid)
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Pour point	Not available.
Specific gravity	1.0027 g/mL (liquid)
Partition coefficient (n-octanol/water)	Not available.
Flash point	> 212.0 °F (> 100.0 °C) Tag Closed Cup (Liquid)
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Wipe is not soluble
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and Reactivity

Reactivity	May react with incompatible materials.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Chemical stability	Stable under recommended storage conditions.
Conditions to avoid	Avoid temperatures exceeding the flash point. Do not mix with other chemicals. Contact with incompatible materials.
Incompatible materials	Acids. Oxidizers. Caustics.
Hazardous decomposition products	May include and are not limited to: Oxides of carbon. Chloride compounds Ammonia.

11. Toxicological Information

Information on likely routes of exposure

Ingestion	Not applicable under normal conditions of use.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Prolonged skin contact may cause skin irritation.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	Symptoms may include stinging, tearing, redness, swelling of the eyes, and blurred vision. Symptoms may include redness, drying, defatting and cracking of the skin. Symptoms may include stomach distress, nausea or vomiting.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Benzyl-C12-18-alkyldimethyl ammonium chlorides (CAS 68391-01-5)		
Acute		
Dermal		
LD50	Rat	2000 mg/kg
		1420 mg/kg
Inhalation		
LC50	Not available	
Oral		
LD50	Mouse	150 mg/kg
	Rat	240 mg/kg
Quaternary ammonium compounds, C12-14-alkyl[(ethylphenyl)methyl]dimethyl, chlorides (CAS 85409-23-0)		
Acute		
Dermal		
LD50	Not available	
Inhalation		
LC50	Not available	
Oral		
LD50	Rat	300 - 2000 mg/kg

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Exposure minutes	Not available.
Erythema value	Not available.
Oedema value	Not available.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Corneal opacity value	Not available.
Iris lesion value	Not available.
Conjunctival reddening value	Not available.
Conjunctival oedema value	Not available.
Recover days	Not available.
Respiratory or skin sensitization	
Respiratory sensitization	Not available.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	Non-hazardous by OSHA criteria.
Carcinogenicity	Non-hazardous by OSHA criteria.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	Non-hazardous by OSHA criteria.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Chronic effects	Non-hazardous by OSHA criteria.
Further information	This product has no known adverse effect on human health.

12. Ecological Information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. See below
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Mobility in general	Not available.

Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions	Dispose of used towelette in trash. Do not flush in toilet.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	This product is not a hazardous waste.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty packaging may be disposed in trash.

14. Transport Information

U.S. Department of Transportation (DOT)

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations

This product is NOT known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

PRECAUTIONARY STATEMENTS: Hazard to humans and domestic animals.
CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or tobacco. Remove contaminated clothing and wash before reuse.

EPA Reg. # 61178-4-9480
EPA Est. # 9480-NY-1.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.

US state regulations

This product is not subject to warning labeling under the California Proposition 65 regulation.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US - Texas Effects Screening Levels: Listed substance

Benzyl-C12-18-alkyldimethyl ammonium chlorides (CAS 68391-01-5) Listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

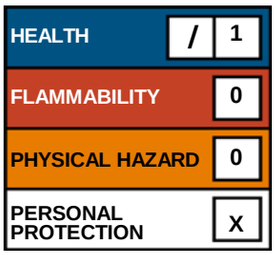
Not regulated.

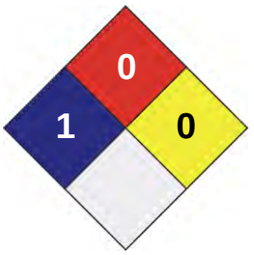
Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

16. Other Information

LEGEND	
Severe	4
Serious	3
Moderate	2
Slight	1
Minimal	0





Disclaimer

The information in the sheet was written based on the best knowledge and experience currently available. Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

Issue date

11-February-2015

Further information

For any questions surrounding this SDS, please contact the supplier/manufacturer listed on the first page of the document.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Not for use on skin. Not a baby wipe. For use on hard surfaces only.

Revision 0.
Bulk Liquid # 4BQ08401.

Other information

This Safety Data Sheet was prepared to comply with the current OSHA Hazard Communication Standard (HCS) adoption of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Prepared by

Dell Tech Laboratories, Ltd. Phone: (519) 858-5021

POLYMEDCO, INC. Safety Data Sheet

Sed-Chek® 2 Erythrocyte Sedimentation Rate Controls

Section 1 Identification	
Product name	Sed-Chek® 2 Erythrocyte Sedimentation Rate Controls; Normal, Abnormal, and Bilevel Sed-Chek® 2 Erythrocyte Sedimentation Rate Controls; for StaRRsed, Normal and Abnormal Sed-Chek® 2 Erythrocyte Sedimentation Rate Controls for Sedimat® 15; Normal, Abnormal, and Bilevel
Catalog number	ESR-2CT, ESR-2CTA, ESR-2CTN, ESR-2CT-E, ESR-2SSA, ESR-2SSN, ESR-5CT, ESR-5CTA, ESR-5CTN, ESR-5CT-E
Recommended use	Control for erythrocyte sedimentation rate testing, normal and abnormal levels
Distributed by	Polymedco, Inc. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Potentially biohazardous material
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	This product is derived from human source material. Each human donor unit used to manufacture this product was tested and found non-reactive per current applicable FDA requirements using FDA-accepted methods including testing for HIV-1 / HIV-2 Antibody, HBsAg, HCV Antibody, HIV-1 and HCV by a nucleic acid test (NAT). No test can offer complete assurance that infectious agents are absent, so handle this product as potentially biohazardous material.

Section 3 Composition and Information on Ingredients	
Chemical characterization	Human erythrocytes suspended in solution with non-hazardous components
Chemical name	Not applicable
Synonyms	Not applicable
CAS number	Not applicable
Concentration	Not applicable

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Get medical advice / attention if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill. Decontaminate spill area with bleach or other suitable disinfectant.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	Room temperature
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not listed
ACGIH	Not listed
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Red liquid in mixed state; layered red and clear liquid in settled state
Odor	Odorless
Odor threshold	Not determined
pH	7.0 – 9.0
Melting point / Freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	None identified
Hazardous reactions	None identified
Hazardous polymerization	Will not polymerize
Incompatibilities	Not determined
Hazard decomposition products	Not determined
Conditions to avoid	None identified

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	Not determined
Ingestion	None identified
Skin contact	None identified
Eye contact	None identified
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof container marked with biohazard symbol. Dispose of broken glass vials in medical sharps container or equivalent
Disposal methods	Dispose in biohazardous or medical waste, in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Potentially biohazardous material; dispose in biohazardous or medical waste
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Dispose in biohazardous or medical waste

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Not listed
SARA	
302	Not applicable
311/312	No hazards
313	Not applicable
CERCLA RQ	Not applicable
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
EINECS Number	268-338-3
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards	Potential biohazard	Protective Equipment	B
Date of preparation	05 September 2014		
Last revision date	9 March 2015		
The information in this SDS is believed to be accurate and complete at the time of revision. No warranty, express or implied, is made, and Polymedco assumes no legal responsibility or liability from its use. The user of our products is responsible for observing any applicable laws and guidelines.			

POLYMEDCO, INC. Safety Data Sheet

Sediplast® Tubes with Diluent

Section 1 Identification	
Product name	Sediplast® Tubes with Diluent
Catalog number	S-100, S-1000, S-1000-B, S-250, S-VIAL, S-10E
Recommended use	Diluent: Anticoagulant for whole blood samples
Distributed by	Polymedco, Inc. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	Not applicable

Section 3 Composition and Information on Ingredients	
Chemical characterization	Aqueous solution
Chemical name	Sodium citrate
Synonyms	Sodium Citrate Dihydrate Trisodium Citrate
CAS number	6132-04-3
Concentration	3.8% in water

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Get medical advice / attention if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	May emit fumes of carbon and sodium oxides
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	Room temperature
Incompatibilities	Strong oxidizing agents

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not listed
ACGIH	Not listed
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties	
Appearance	Clear colorless liquid
Odor	Odorless
Odor threshold	Not determined
pH	5.65
Melting point / Freezing point	Approximately 0°C
Initial boiling point and boiling range	Approximately 100°C
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Soluble in water
Partition coefficient	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	None identified
Hazardous reactions	None identified
Hazardous polymerization	Will not polymerize
Incompatibilities	Strong oxidizing agents
Hazard decomposition products	Carbon oxides
Conditions to avoid	None identified

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	Not determined
Ingestion	None identified
Skin contact	May cause irritation, but unlikely at the concentration present
Eye contact	May cause irritation, but unlikely at the concentration present
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not listed as a carcinogen or potential carcinogen by ACGIH, IARC, NTP, or CA Prop 65
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

Section 12 Ecological Information	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	No special containers required
Disposal methods	Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	None identified
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	None identified

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Mixture (hydrate) of item listed on TSCA Inventory. Not listed under Section 12b.
SARA	
302	Not applicable
311/312	No hazards
313	Not applicable
CERCLA RQ	Not applicable
CA Prop 65	Not listed
Canada DSL/NDSL	Mixture (hydrate) of item listed on DSL
WHMIS Class	Not applicable
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	1	Health	1
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards		Protective Equipment	B
Date of preparation	02 September 2014		
Last revision date	26 February 2015		
The information in this SDS is believed to be accurate and complete at the time of revision. No warranty, express or implied, is made, and Polymedco assumes no legal responsibility or liability from its use. The user of our products is responsible for observing any applicable laws and guidelines.			

BECKMAN COULTER
Serum Protein Multicalibrator

SAFETY DATA SHEET

Document ID: ODR3021-75 Version 05
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Serum Protein Multicalibrator

Part Number ODR3021

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Amber; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Serum Protein Multicalibrator

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Section 2 Hazards (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Serum Protein Multicalibrator

SAFETY DATA SHEET
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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses — No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA — None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH — None established

Japan — None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls — No special engineering controls are required. Use with good general ventilation.

Eye Protection — Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection — Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection — Under normal conditions, the use of this product should not require respiratory protection.

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Serum Protein Multicalibrator

SAFETY DATA SHEET

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Amber	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	7 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

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Serum Protein Multicalibrator

SAFETY DATA SHEET

Document ID: ODR3021-75 Version 05
Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Serum Protein Multicalibrator

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Last Revision Date (year/month/day) 2015/03/20

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-10-3	Neomycin Sulfate
CAS # 3810-74-0	Streptomycin Sulphate
CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 56-75-7	Chloramphenicol
CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 56-75-7	Chloramphenicol
CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

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Last Revision Date (year/month/day) 2015/03/20

Section 15 Regulatory Information (Continued)

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated the label elements in Sec. 2.2.
Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1.
Updated hazardous ingredients in Section 3.
Updated Section 15 Regulatory Information.
Updated section 4, 6, 8, 10, 11, 14, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/03/12
Last Revision Date (year/month/day) 2015/03/20
Document ID: ODR3021-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program

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Section 16 Other Information (Continued)

OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SECTION 1: Identification

1.1. Product Identifier

Trade Name or Designation: Sodium Chloride, 0.9% (w/v), pH 7.25-7.35

Product Number: 7211
Other Identifying Product Numbers: 7211-5

1.2. Recommended Use and Restrictions on Use

General Laboratory Reagent

1.3. Details of the Supplier of the Safety Data Sheet

Company: Ricca Chemical Company

Address: 448 West Fork Drive
Arlington, TX 76012 USA
Telephone: 888-467-4222

1.4. Emergency Telephone Number (24 hr)

CHEMTREC (USA) 800-424-9300
CHEMTREC (International) 1+ 703-527-3887

SECTION 2: Hazard(s) Identification

2.1. Classification of the Substance or Mixture (in accordance with OSHA HCS 29 CFR 1910.1200)

For the full text of the Hazard and Precautionary Statements listed below, see Section 16.

This product is not categorized as hazardous in any GHS hazard class.

2.2. GHS Label Elements

Pictograms: None required.

Signal Word: None required.

Hazard Statements: None required.

Precautionary Statements: None required.

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2.3. WHMIS Classification

WHMIS classification is not included based on the recommended option (Option 4) found in the Canada Gazette Part II, Vol. 149, No.3, page 458

2.4. Hazards not Otherwise Classified or Covered by GHS

Data not available.

SECTION 3: Composition / Information on Ingredients

3.1. Components of Substance or Mixture

Chemical Name	Formula	Molecular Weight	CAS Number	Weight%
Water	H_2O	18.01 g/mol	7732-18-5	99.10%
Sodium Chloride	NaCl	58.44 g/mol	7647-14-5	0.90%
Sodium Bicarbonate	$NaHCO_3$	84.00 g/mol	144-55-8	0.00%

SECTION 4: First-Aid Measures

4.1. General First Aid Information

Eye Contact: May cause irritation, redness, pain, and tearing.

Inhalation: Not expected to require first aid. If necessary, remove to fresh air.

Skin Contact: May cause irritation, redness, itching and pain, especially on damaged or broken skin.

Ingestion: Dilute with water or milk. Do not induce vomiting. Call a physician if necessary.

4.2. Most Important Symptoms and Effects, Acute and Delayed

May cause irritation to the eyes and skin. Wash areas of contact with water. Call a physician if irritation develops. Does not present any significant health hazards. EYE CONTACT: May cause irritation, redness, pain, and tearing. SKIN CONTACT: May cause irritation, redness, itching and pain, especially on damaged or broken skin.

4.3. Medical Attention or Special Treatment Needed

Not expected to require special treatment.

SECTION 5: Fire-Fighting Measures

5.1. Extinguishing Media

Use any means suitable for extinguishing surrounding fire.

5.2. Specific Hazards Arising from the Substance or Mixture

Not considered to be a fire or explosion hazard.

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5.3. Special Protective Equipment for Firefighters

Use protective clothing and breathing equipment appropriate for the surrounding fire.

SECTION 6: Accidental Release Measures

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Wear appropriate PPE for the size and nature of the spill. As a general rule, wear safety glasses and gloves.

6.2. Cleanup and Containment Methods and Materials

Absorb with suitable material and treat as normal refuse. Small amounts of the liquid may be flushed to the drain with excess water. Always dispose of in accordance with local regulations.

SECTION 7: Handling and Storage

7.1. Precautions for Safe Handling and Storage Conditions

As with all chemicals, wash hands thoroughly after handling. Avoid contact with eyes and skin. Protect from freezing and physical damage.

SECTION 8: Exposure Controls / Personal Protection

8.2. Exposure Controls

Engineering Controls: No specific controls are needed. Normal room ventilation is adequate.

Respiratory Protection: Normal room ventilation is adequate.

Skin Protection: Chemical resistant gloves.

Eye Protection: Safety glasses or goggles.

8.3. Personal Protective Equipment

Normal room ventilation is adequate. Chemical resistant gloves. Safety glasses or goggles.

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SECTION 9: Physical and Chemical Properties

9.1. Basic Physical and Chemical Properties

Appearance:	Colorless liquid
Physical State:	Liquid
Odor:	Data not available.
Odor Threshold:	Data not available.
pH:	7.3
Melting/Freezing Point:	0.0°C
Initial Boiling Point /Range:	100°C - 100°C
Flash Point:	Data not available.
Evaporation Rate:	Data not available.
Flammability:	Data not available.
Flammability/Explosive Limits:	Data not available.
Vapor Pressure:	Data not available.
Vapor Density:	Data not available.
Relative Density:	1.0
Solubility:	Miscible
Partition Coeffieient (n-Octanol/Water):	Data not available.
Auto-Ignition Temperature:	Data not available.
Decomposition Temperature:	Data not available.
Viscosity:	Data not available.
ExplosiveProperties:	Data not available.
Oxidizing Properties:	Data not available.

SECTION 10: Stability and Reactivity

10.1. Reactivity and Chemical Stability

Stable under normal conditions of use and storage.

10.2. Possibility of Hazardous Reactions

Data not available.

10.3. Conditions to Avoid and Incompatible Materials

Strong oxidizing agents, Lithium, Bromine Trifluoride.

10.4. Hazardous Decomposition Products

Will not occur.

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SECTION 11: Toxicological Information

11.1. Information on Toxicological Effects

Acute Toxicity - Oral Exposure:

Not applicable.

Acute Toxicity - Dermal Exposure:

Not applicable.

Acute Toxicity - Inhalation Exposure:

Not applicable.

Acute Toxicity - Other Information:

LD50, Oral, Rat: (Sodium Chloride) 3000 mg/kg, details of toxic effects not reported other than lethal dose value. LD50, Dermal, Rabbit: (Sodium Chloride) >10 gm/kg.

Skin Corrosion and Irritation:

Not applicable.

Serious Eye Damage and Irritation:

Not applicable.

Respiratory Sensitization:

Not applicable.

Skin Sensitization:

Not applicable.

Germ Cell Mutagenicity:

Not applicable.

Carcinogenicity:

Not applicable.

Reproductive Toxicity:

Not applicable.

Specific Target Organ Toxicity from Single Exposure:

Not applicable.

Specific Target Organ Toxicity from Repeated Exposure:

Not applicable.

Aspiration Hazard:

Not applicable.

Additional Toxicology Information:

Data not available.

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SECTION 12: Ecological Information

12.1. Ecotoxicity

Not applicable.

12.2. Persistence and Degradability

Data not available.

12.3. Bioaccumulative Potential

Data not available.

12.4. Mobility in Soil

Data not available.

12.5. Other Adverse Ecological Effects

Data not available.

SECTION 13: Disposal Considerations

13.1. Waste Treatment Methods

Data not available.

SECTION 14: Transportation Information

14.1. Transportation by Land - Department of Transportation (DOT, United States of America)

Not regulated according to DOT Regulations.

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Not regulated according to IATA Regulations.

SECTION 15: Regulatory Information

15.1. Occupational Safety and Health Administration (OSHA) Hazards

Not listed.

15.2. Superfund Amendments and Reauthorization Act (SARA) 302 Extremely Hazardous Substances

Not listed.

15.3. Superfund Amendments and Reauthorization Act (SARA) 311/312 Hazardous Chemicals

Not listed.

15.4. Superfund Amendments and Reauthorization Act (SARA) 313 Toxic Release Inventory (TRI)

Not listed.

15.5. Massachusetts Right-to-Know Substance List

Not listed.

15.6. Pennsylvania Right-to-Know Hazardous Substances

Water (CAS # 7732-18-5): Present

15.7. New Jersey Worker and Community Right-to-Know Components

Not listed.

15.8. California Proposition 65

Not listed.

15.9. Canada Domestic Substances List / Non-Domestic Substances List (DSL/NDSL)

Sodium Bicarbonate (CAS # 144-55-8): Present (DSL)
Sodium Chloride (CAS # 7647-14-5): Present (DSL)
Water (CAS # 7732-18-5): Present (DSL)

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15.10. United States of America Toxic Substances Control Act (TSCA) List

Sodium Bicarbonate (CAS # 144-55-8): Present
Sodium Chloride (CAS # 7647-14-5): Present
Water (CAS # 7732-18-5): Present

15.11. European Inventory of Existing Commercial Chemical Substances (EINECS), European List of Notified Chemical Substances (ELINCS), and No Longer Polymers (NLP)

Not listed.

SECTION 16: Other Information

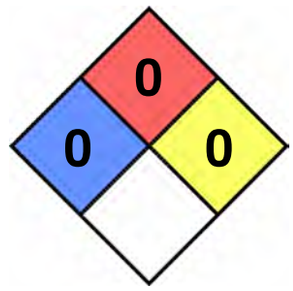
16.1. Full Text of Hazard Statements and Precautionary Statements

16.2. Miscellaneous Hazard Classes

Canadian Carcinogenicity Hazard Class: Not Applicable.
Physical Hazards Not Otherwise Classified (PHNOC): Not Applicable.
Health Hazards Not Otherwise Classified (HHNOC): Not Applicable.
Not Applicable.

16.3. National Fire Protection Association (NFPA) Rating

Health: 0
Flammability: 0
Reactivity: 0
Special Hazard:



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Safety Data Sheet

16.4. Document Revision

Last Revision Date: 5/1/2015

DISCLAIMER

When handled properly by qualified personnel, the product described herein does not present a significant health or safety hazard. Alteration of its characteristics by concentration, evaporation, addition of other substances, or other means may present hazards not specifically addressed herein and which must be evaluated by the user. The information furnished herein is believed to be accurate and represents the best data currently available to us. No warranty, expressed or implied, is made and RICCA CHEMICAL COMPANY assumes no legal responsibility or liability whatsoever resulting from its use.

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A32320 Rev. AF
Revised (year/month/day) 2016/09/29

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sodium Hypochlorite Solution

Part Number A32319, S1315

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For laboratory use only. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	**EC REP Address**
Manufactured for Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Eurocenter S.A. 22, rue Juste-Oliver, Case Postale 1044, CH-1260 Nyon 1, Switzerland. Telephone +41 (0)22 365 36 11 Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellow-green; Clear; Liquid; Chlorine-like

Classification according to EC 1272/2008 (CLP/GHS)

Skin Irritation Category 2
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

C;R31-34; N;R50

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 2
Eye Damage Category 1
Aquatic Hazard Acute, Category 2

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hydroxide
Sodium Hypochlorite

Pictogram

Signal Word

DANGER

Hazard Statements

H315 Causes skin irritation.
H401 Toxic to aquatic life
H318 Causes serious eye damage.

Precautionary Statements

P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P501 Dispose of contents/container in accordance with local/national regulations
P310 Immediately call a POISON CENTER or doctor/physician.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Hypochlorite CAS # 7681-52-9 EINECS # 231-668-3 Index # 017-011-00-1	4 - 7	C;R31-34 N;R50	Aquatic Acute 1 Eye Dam. 1 Skin Corr. 1B H314; H318; H400	Aquatic Acute 1 Eye Dam. 1 Skin Corr. 1B H314; H318; H400	

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Hydroxide CAS # 1310-73-2 EINECS # 215-185-5 Index # 011-002-00-6	<1	C;R 35	Eye Dam. 1 Skin Corr. 1A H314; H318	Eye Dam. 1 Skin Corr. 1A H314; H318	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes skin irritation.

Causes serious eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at Room Temperature, as directed on the Product Label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sodium Hydroxide
CAS # 1310-73-2 — 2 mg/m3 TWA

ACGIH

Sodium Hydroxide
CAS # 1310-73-2 — 2 mg/m3 Ceiling

DFG MAK None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Ireland

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 STEL
IOELVs	None established
NIOSH	
Sodium Hydroxide CAS # 1310-73-2	10 mg/m3 IDLH
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.08 @20°C
Color	Yellow-green	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Chlorine-like	**Organic**	Not determined
pH	12 - 12.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	2.3 kPa @20°C
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hydroxide CAS # 1310-73-2	Dermal LD50 Rabbit 1350 mg/kg
Sodium Hypochlorite CAS # 7681-52-9	Oral LD50 Rat 8200 mg/kg; Dermal LD50 Rabbit >10000 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation May cause skin irritation.

Serious eye damage/eye irritation Contact may cause serious eye damage.

Respiratory/skin sensitization Not classified based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not classified based on available data.

Reproductive Toxicity Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard — Not classified based on available data.

Other Information — No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hydroxide CAS # 1310-73-2	96 h LC50 Oncorhynchus mykiss: 45.4 mg/L [static]
Sodium Hypochlorite CAS # 7681-52-9	96 h LC50 Pimephales promelas: 0.06 - 0.11 mg/L [flow-through]; 96 h LC50 Pimephales promelas: 4.5 - 7.6 mg/L [static]; 96 h LC50 Lepomis macrochirus: 0.4 - 0.8 mg/L [static]; 96 h LC50 Lepomis macrochirus: 0.28 - 1 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 0.05 - 0.771 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 0.03 - <0.19 mg/L [semi-static]; 96 h LC50 Oncorhynchus mykiss: 0.18 - 0.22 mg/L [static]

Microtox — No information available.

Water Flea

Sodium Hypochlorite CAS # 7681-52-9	96 h EC50 Daphnia magna: 2.1 mg/L; 48 h EC50 Daphnia magna: 0.033 - 0.044 mg/L [Static]

Fresh Water Algae — No information available.

12.2 Persistence and degradability — Not determined for the product.

12.3 Bioaccumulation — Not determined for the product.

12.4 Mobility in soil — Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects — This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal — Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2 Additional information	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
CERCLA RG's, 40 CFR 302.4	Sodium Hydroxide is listed. Sodium Hypochlorite is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Hydroxide is listed. Sodium Hypochlorite is listed.
New Jersey Dept. of Health RTK List	Sodium Hydroxide is listed. Sodium Hypochlorite is listed.
Pennsylvania RTK	Sodium Hydroxide is listed. Sodium Hypochlorite is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 2, water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Corrosive
C

Dangerous for the environment
N

Risk and Safety Phrases

R31 Contact with acids liberates toxic gas.
R50 Very toxic to aquatic organisms.
R34 Causes burns.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.
S28 After contact with skin, wash immediately with plenty of water.

Canada

WHMIS Classification: E - Corrosive Material

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Hydroxide
Sodium Hypochlorite

Ingredients with unknown toxicological properties

None

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Update of product hazard classifications and label elements in Sec. 2.
Updated Section 4.
Updated Section 7.
Updated Section 8.
Updated Section 9.
Updated Section 11.
Updated Section 14.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
N - Dangerous for the environment
R 35 Causes severe burns.
R31 Contact with acids liberates toxic gas.

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Section 16 Other Information (Continued)

	R34 Causes burns. R50 Very toxic to aquatic organisms. Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Eye Dam. 1 - Eye Damage Category 1 Skin Corr. 1A - Skin Corrosion Category 1A Skin Corr. 1B - Skin Corrosion Category 1B H314 - Causes severe skin burns and eye damage. H318 - Causes serious eye damage. H400 - Very toxic to aquatic life.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LD50 - Lethal Dose, 50% LC50 - Lethal Concentration, 50% EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Version: 2.0
Revision Date: 03/18/2020

SAFETY DATA SHEET

1. Identification

Product identifier: SPRAYWAY GLASS CLEANER

Other means of identification
SDS number: RE1000000075

Recommended restrictions
Product use: Cleaner
Restrictions on use: Not known.

Manufacturer/Importer/Distributor Information

Manufacturer

Company Name:	Sprayway, Inc.
Address:	1000 INTEGRAM DR. Pacific, MO 63069
Telephone:	1-630-628-3000
Fax:	

Emergency telephone number: 1-866-836-8855

2. Hazard(s) identification

Hazard Classification

Physical Hazards

Gases under pressure	Compressed gas

Label Elements

Hazard Symbol:

Signal Word:	Warning
Hazard Statement:	Contains gas under pressure; may explode if heated.
Precautionary Statements	
Storage:	Protect from sunlight. Store in a well-ventilated place.
Hazard(s) not otherwise classified (HNOC):	None.

3. Composition/information on ingredients

Mixtures

Chemical Identity	CAS number	Content in percent (%)*
Ethanol	64-17-5	1 - <5%
Ethanol, 2-butoxy-	111-76-2	1 - <5%
Propane	74-98-6	1 - <5%
Butane	106-97-8	1 - <5%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Ingestion: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

Inhalation: Move to fresh air.

Skin Contact: Wash skin thoroughly with soap and water. If skin irritation occurs: Get medical advice/attention.

Eye contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. If eye irritation persists: Get medical advice/attention.

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Hazards: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Use water spray to keep fire-exposed containers cool. Fight fire from a protected location. Move containers from fire area if you can do so without risk.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media: Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical: Pressurized container may explode when exposed to heat or flame.

Special protective equipment and precautions for firefighters

Special fire fighting procedures: No data available.

Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: No data available.

Methods and material for containment and cleaning up: Stop the flow of material, if this is without risk. Absorb with sand or other inert absorbent.

Environmental Precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water sources or sewer. Environmental manager must be informed of all major spillages.

7. Handling and storage

Precautions for safe handling: Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities: Protect from sunlight. Store in a cool place. Aerosol Level 1

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

Chemical Identity	Type	Exposure Limit Values	Source
Ethanol	REL	1,000 ppm 1,900 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	PEL	1,000 ppm 1,900 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
	TWA	1,000 ppm 1,900 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	STEL	1,000 ppm	US. ACGIH Threshold Limit Values (2009)
Ethanol, 2-butoxy-	TWA	20 ppm	US. ACGIH Threshold Limit Values (2008)
	REL	5 ppm 24 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	PEL	50 ppm 240 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
	TWA	25 ppm 120 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
Propane	REL	1,000 ppm 1,800 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	PEL	1,000 ppm 1,800 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
	TWA	1,000 ppm 1,800 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
Butane	REL	800 ppm 1,900 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	STEL	1,000 ppm	US. ACGIH Threshold Limit Values (03 2018)
	TWA	800 ppm 1,900 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
Morpholine	REL	20 ppm 70 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	STEL	30 ppm 105 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	TWA	20 ppm	US. ACGIH Threshold Limit Values (2008)
	TWA	20 ppm 70 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	STEL	30 ppm 105 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)

	PEL	20 ppm	70 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
2-Propanol, 2-methyl-	STEL	150 ppm	450 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	TWA	100 ppm	300 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	PEL	100 ppm	300 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
	TWA	100 ppm		US. ACGIH Threshold Limit Values (2008)
	STEL	150 ppm	450 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	REL	100 ppm	300 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
Silica	REL		6 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	TWA		20 millions of particles per cubic foot of air	US. OSHA Table Z-3 (29 CFR 1910.1000) (2000)
	TWA		6 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	TWA		0.8 mg/m3	US. OSHA Table Z-3 (29 CFR 1910.1000) (2000)
2,6-Octadienal, 3,7-dimethyl- - Inhalable fraction and vapor.	TWA	5 ppm		US. ACGIH Threshold Limit Values (01 2010)

Biological Limit Values

Chemical Identity	Exposure Limit Values	Source
Ethanol, 2-butoxy- (Butoxyacetic acid (BAA), with hydrolysis: Sampling time: End of shift.)	200 mg/g (Creatinine in urine)	ACGIH BEL (03 2013)

Appropriate Engineering Controls No data available.

Individual protection measures, such as personal protective equipment

General information: Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection: Wear goggles/face shield.

Skin Protection
Hand Protection: No data available.

Other: No data available.

Respiratory Protection: In case of inadequate ventilation use suitable respirator. Seek advice from local supervisor.

Hygiene measures: Observe good industrial hygiene practices.

9. Physical and chemical properties

Appearance

Physical state: liquid
Form: Spray Aerosol
Color: No data available.
Odor: No data available.
Odor threshold: No data available.
pH: 8.7 - 9.7
Melting point/freezing point: No data available.
Initial boiling point and boiling range: No data available.

Flash Point:	Not applicable
Evaporation rate:	No data available.
Flammability (solid, gas):	Non-flammable Aerosol
Upper/lower limit on flammability or explosive limits	
Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Explosive limit - upper (%):	No data available.
Explosive limit - lower (%):	No data available.
Vapor pressure:	5,515 - 6,894 hPa (20 °C)
Vapor density:	No data available.
Density:	No data available.
Relative density:	No data available.
Solubility(ies)	
Solubility in water:	No data available.
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.

10. Stability and reactivity

Reactivity:	No data available.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	No data available.
Conditions to avoid:	Avoid heat or contamination.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	No data available.

11. Toxicological information

Information on likely routes of exposure

Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.
Ingestion:	No data available.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.

Ingestion: No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: ATEmix: 36,844.23 mg/kg

Dermal
Product: ATEmix: 32,120.9 mg/kg

Inhalation
Product: ATEmix: 690.87 mg/l
ATEmix : 172.72 mg/l

Repeated dose toxicity
Product: No data available.

Specified substance(s):

Ethanol	NOAEL (Rat(Male), Oral, 7 - 14 Weeks): 10 %(m) Oral Experimental result, Key study
Ethanol, 2-butoxy-	NOAEL (Rat(Female), Inhalation, 2 yr): < 31 ppm(m) Inhalation Experimental result, Key study NOAEL (Rat(Female), Oral, 90 d): < 82 mg/kg Oral Experimental result, Key study NOAEL (Rabbit(Female, Male), Dermal, 90 d): > 150 mg/kg Dermal Experimental result, Key study
Propane	NOAEL (Rat(Female, Male), Inhalation, >= 28 d): 4,000 ppm(m) Inhalation Experimental result, Key study LOAEL (Rat(Female, Male), Inhalation, >= 28 d): 12,000 ppm(m) Inhalation Experimental result, Key study
Butane	LOAEL (Rat(Female, Male), Inhalation, >= 28 d): 12,000 ppm(m) Inhalation Experimental result, Key study NOAEL (Rat(Female, Male), Inhalation, >= 28 d): 4,000 ppm(m) Inhalation Experimental result, Key study

Skin Corrosion/Irritation
Product: No data available.

Specified substance(s):

Ethanol	in vivo (Rabbit): Not irritant Experimental result, Key study
Ethanol, 2-butoxy-	in vivo (Rabbit): Irritating Experimental result, Key study

Serious Eye Damage/Eye Irritation
Product: No data available.

Specified substance(s):

Ethanol	Rabbit, 1 - 24 hrs: Not irritating
Ethanol, 2-butoxy-	Rabbit, 24 - 72 hrs: Irritating

Respiratory or Skin Sensitization
Product: No data available.

Specified substance(s):

Ethanol	Skin sensitization:, in vivo (Guinea pig): Non sensitising
Ethanol, 2-butoxy-	Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity
Product: No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro
Product: No data available.

In vivo
Product: No data available.

Reproductive toxicity
Product: No data available.

Specific Target Organ Toxicity - Single Exposure
Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure
Product: No data available.

Aspiration Hazard
Product: No data available.

Other effects: No data available.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish
Product: No data available.

Specified substance(s):

Ethanol	LC 50 (Pimephales promelas, 96 h): 15.3 g/l Experimental result, Key study
Ethanol, 2-butoxy-	LC 50 (Oncorhynchus mykiss, 96 h): 1,474 mg/l Experimental result, Key study
Propane	LC 50 (Various, 96 h): 147.54 mg/l QSAR QSAR, Key study
Butane	LC 50 (Various, 96 h): 147.54 mg/l QSAR QSAR, Key study

Aquatic Invertebrates
Product: No data available.

Specified substance(s):

Ethanol	LC 50 (Ceriodaphnia dubia, 48 h): 5,012 mg/l Experimental result, Key study
Ethanol, 2-butoxy-	EC 50 (Daphnia magna, 48 h): 1,550 mg/l Experimental result, Key study
Butane	LC 50 (Daphnia sp., 48 h): 69.43 mg/l QSAR QSAR, Key study

Chronic hazards to the aquatic environment:

Fish

Product:	No data available.
Specified substance(s):	
Ethanol	NOAEL (Oryzias latipes): 7,900 mg/l Read-across from supporting substance (structural analogue or surrogate), Supporting study
Ethanol, 2-butoxy-	NOAEL (Danio rerio): > 100 mg/l Experimental result, Key study

Aquatic Invertebrates

Product:	No data available.
Specified substance(s):	
Ethanol	LC 50 (Daphnia magna): 454 mg/l Experimental result, Key study NOAEL (Daphnia magna): 9.6 mg/l Experimental result, Key study
Ethanol, 2-butoxy-	EC 10 (Daphnia magna): 134 mg/l Experimental result, Key study EC 50 (Daphnia magna): 297 mg/l Experimental result, Key study

Toxicity to Aquatic Plants

Product:	No data available.

Persistence and Degradability

Biodegradation

Product:	No data available.
Specified substance(s):	
Ethanol	95 % Detected in water. Experimental result, Key study
Ethanol, 2-butoxy-	90.4 % Detected in water. Experimental result, Key study
Propane	100 % (385.5 h) Detected in water. Experimental result, Key study 50 % (3.19 d) Detected in water. QSAR, Weight of Evidence study
Butane	100 % (385.5 h) Detected in water. Experimental result, Key study

BOD/COD Ratio

Product:	No data available.

Bioaccumulative potential

Bioconcentration Factor (BCF)

Product:	No data available.
Specified substance(s):	
Ethanol	Cyprinus carpio, Bioconcentration Factor (BCF): 4.5 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study

Partition Coefficient n-octanol / water (log Kow)

Product:	No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Ethanol	No data available.
Ethanol, 2-butoxy-	No data available.
Propane	No data available.
Butane	No data available.

Other adverse effects: No data available.

13. Disposal considerations

Disposal instructions: Wash before disposal. Dispose to controlled facilities.

Contaminated Packaging: No data available.

14. Transport information

DOT

UN Number:	UN 1950
UN Proper Shipping Name:	Aerosols, non-flammable
Transport Hazard Class(es)	
Class:	2.2
Label(s):	–
Packing Group:	II
Marine Pollutant:	No
Environmental Hazards:	No
Marine Pollutant	No
Special precautions for user:	Not regulated.

IMDG

UN Number:	UN 1950
UN Proper Shipping Name:	Aerosols, non-flammable
Transport Hazard Class(es)	
Class:	2
Label(s):	–
EmS No.:	
Packing Group:	–
Environmental Hazards:	No
Marine Pollutant	No
Special precautions for user:	Not regulated.

IATA

UN Number:	UN 1950
Proper Shipping Name:	Aerosols, non-flammable
Transport Hazard Class(es):	
Class:	2.2
Label(s):	–
Packing Group:	–
Environmental Hazards:	No
Marine Pollutant	No
Special precautions for user:	Not regulated.
Cargo aircraft only:	Allowed.

15. Regulatory information

US Federal Regulations

Restrictions on use: Not known.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

Chemical Identity	Reportable quantity
Ethanol	lbs. 100
Propane	lbs. 100
Butane	lbs. 100
Morpholine	lbs. 100
Nitrous acid, sodium salt (1:1)	lbs. 100
2-Propanol, 2-methyl-	lbs. 100

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Not listed.

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

Chemical Identity	Reportable quantity
Ethanol	lbs. 100
Ethanol, 2-butoxy-	
Propane	lbs. 100
Butane	lbs. 100
Morpholine	lbs. 100
Nitrous acid, sodium salt (1:1)	lbs. 100
2-Propanol, 2-methyl-	lbs. 100

SARA 311/312 Hazardous Chemical

Chemical Identity	Threshold Planning Quantity
Ethanol	10000 lbs
Ethanol, 2-butoxy-	10000 lbs
Propane	10000 lbs
Butane	10000 lbs
Morpholine	10000 lbs
Nitrous acid, sodium salt (1:1)	10000 lbs
2-Propanol, 2-methyl-	10000 lbs
Silica	10000 lbs
2,6-Octadienal, 3,7-dimethyl-	10000 lbs

SARA 313 (TRI Reporting)

Chemical Identity	Reporting threshold for other users	Reporting threshold for manufacturing and processing
Ethanol, 2-butoxy-	N230 lbs	N230 lbs.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

US State Regulations

US. California Proposition 65

No ingredient requiring a warning under CA Prop 65.

US. New Jersey Worker and Community Right-to-Know Act

Chemical Identity

Ethanol
Ethanol, 2-butoxy-
Propane
Butane

US. Massachusetts RTK - Substance List

No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances

Chemical Identity

Ethanol
Ethanol, 2-butoxy-
Propane
Butane

US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.

International regulations

Montreal protocol

Not applicable

Stockholm convention

Not applicable

Rotterdam convention

Not applicable

Kyoto protocol

Not applicable

Inventory Status:

Australia AICS:	On or in compliance with the inventory
Canada DSL Inventory List:	On or in compliance with the inventory
Canada NDSL Inventory:	Not in compliance with the inventory.
Ontario Inventory:	On or in compliance with the inventory
China Inv. Existing Chemical Substances:	On or in compliance with the inventory
Japan (ENCS) List:	On or in compliance with the inventory
Japan ISHL Listing:	Not in compliance with the inventory.
Japan Pharmacopoeia Listing:	Not in compliance with the inventory.
Korea Existing Chemicals Inv. (KECI):	Not in compliance with the inventory.
Mexico INSQ:	Not in compliance with the inventory.
New Zealand Inventory of Chemicals:	Not in compliance with the inventory.
Philippines PICCS:	Not in compliance with the inventory.
Taiwan Chemical Substance Inventory:	On or in compliance with the inventory
US TSCA Inventory:	On or in compliance with the inventory
EINECS, ELINCS or NLP:	Not in compliance with the inventory.

16.Other information, including date of preparation or last revision

Issue Date:	03/18/2020
Revision Information:	No data available.
Version #:	2.0
Further Information:	No data available.
Disclaimer:	This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.

Safety Data Sheet

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Document group:	10-2819-0	**Version number:**	14.00
Issue Date:	2017/10/04	**Supercedes Date:**	2017/04/07

This Safety Data Sheet has been prepared in accordance with the Canadian Hazardous Products Regulations.

SECTION 1: Identification

1.1. Product identifier
3M™ Stainless Steel Cleaner & Polish

Product Identification Numbers
XN-1015-5591-2 XN-1015-7536-5

1.2. Recommended use and restrictions on use

Recommended use
Metal Polish, Cleans and polishes stainless steel, chrome, aluminum and laminated plastic surfaces.

Restrictions on use
Not Applicable, Not Applicable, Not Applicable

1.3. Supplier's details

Company:	3M Canada Company
Division:	Commercial Solutions Division
Address:	1840 Oxford Street East, Post Office Box 5757, London, Ontario N6A 4T1
Telephone:	(800) 364-3577
Website:	www.3M.ca

1.4. Emergency telephone number
Medical Emergency Telephone: (519) 451-2500, Ext. 2222; Transportation Emergency Telephone (CANUTEC): (613) 996-6666

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture
Flammable Aerosol: Category 1.
Gas Under Pressure: Liquefied gas.
Specific Target Organ Toxicity (single exposure): Category 1.

2.2. Label elements
Signal word
Danger

Symbols
Flame | Gas cylinder | Health Hazard |

Pictograms

Hazard statements
Extremely flammable aerosol. Contains gas under pressure; may explode if heated.

Causes damage to organs: cardiovascular system |

Precautionary statements
General:
Keep out of reach of children. Read label before use. If medical advice is needed, have product container or label at hand.

Prevention:
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

Response:
IF exposed: Call a POISON CENTRE or doctor/physician.

Storage:
Protect from sunlight. Do not expose to temperatures exceeding 50C/122F. Store in a well-ventilated place. Store locked up.

Disposal:
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Other hazards
None known.

11% of the mixture consists of ingredients of unknown acute dermal toxicity.
35% of the mixture consists of ingredients of unknown acute inhalation toxicity.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	C.A.S. No.	% by Wt
Water	7732-18-5	40 - 70
White Mineral Oil (Petroleum)	8042-47-5	10 - 30
Isobutane	75-28-5	7 - 13
Sorbitan Oleate	1338-43-8	0.5 - 1.5
Ethanolamine	141-43-5	0.1 - 1

White Mineral Oil (Petroleum) is a hazardous Trade Secret material according to WHMIS criteria. Refer to Section 15 for further information.
Isobutane is a hazardous Trade Secret material according to WHMIS criteria. Refer to Section 15 for further information.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:
Remove person to fresh air. Get medical attention.

Skin Contact:
Wash with soap and water. If you feel unwell, get medical attention.

Eye Contact:
Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If Swallowed:
Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed
See Section 11.1. Information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required
Exposure may increase myocardial irritability. Do not administer sympathomimetic drugs unless absolutely necessary.

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media
Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture
Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

5.3. Special protective actions for fire-fighters
Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Evacuate area. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Warning! A motor could be an ignition source and could cause flammable gases or vapours in the spill area to burn or explode. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions
Avoid release to the environment.

6.3. Methods and material for containment and cleaning up
If possible, seal leaking container. Place leaking containers in a well-ventilated area, preferably an operating exhaust hood, or if necessary outdoors on an impermeable surface until appropriate packaging for the leaking container or its contents is

available. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible using non-sparking tools. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with water. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Do not use in a confined area with minimal air exchange. Keep out of reach of children. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.)

7.2. Conditions for safe storage including any incompatibilities
Protect from sunlight. Do not expose to temperatures exceeding 50C/122F. Protect from sunlight. Store in a well-ventilated place. Store away from heat. Store away from acids. Store away from oxidizing agents.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	C.A.S. No.	Agency	Limit type	Additional Comments
Ethanolamine	141-43-5	ACGIH	TWA:3 ppm;STEL:6 ppm	
Isobutane	75-28-5	ACGIH	STEL:1000 ppm	
Natural gas	75-28-5	ACGIH	Limit value not established:	
MINERAL OILS, HIGHLY-REFINED OILS	8042-47-5	ACGIH	TWA(inhalable fraction):5 mg/m3	

ACGIH : American Conference of Governmental Industrial Hygienists
AIHA : American Industrial Hygiene Association
CMRG : Chemical Manufacturer's Recommended Guidelines
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls
Do not remain in area where available oxygen may be reduced. Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapours/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety Glasses with side shields

Skin/hand protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing. No chemical protective gloves are required.
Gloves made from the following material(s) are recommended: Nitrile Rubber

Respiratory protection
None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Specific Physical Form:	Aerosol
Appearance/Odour	Thick white emulsion citrus odour
Odour threshold	*No Data Available*
pH	9 - 11
Melting point/Freezing point	*Not Applicable*
Boiling point/Initial boiling point/Boiling range	> 100 ºC
Flash Point	No flash point
Evaporation rate	*No Data Available*
Flammability (solid, gas)	Not Applicable
Flammable Limits(LEL)	*No Data Available*
Flammable Limits(UEL)	*No Data Available*
Vapour Density	*No Data Available*
Density	0.95 g/ml
Relative density	0.92 - 0.98 [*Ref Std:*WATER=1]
Water solubility	Complete
Solubility- non-water	*No Data Available*
Partition coefficient: n-octanol/ water	*No Data Available*
Autoignition temperature	*No Data Available*
Decomposition temperature	*No Data Available*
Viscosity	1,400 - 4,500 mPa-s [*Details:*For Liquid]
Molecular weight	*No Data Available*
Volatile Organic Compounds	10 - 12 % weight [*Test Method:*calculated per CARB title 2]
Percent volatile	75 - 80 % weight
VOC Less H2O & Exempt Solvents	265 - 295 g/l [*Test Method:*calculated per CARB title 2]

SECTION 10: Stability and reactivity

10.1. Reactivity
This material is considered to be non reactive under normal use conditions.

10.2. Chemical stability
Stable.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
Heat
Sparks and/or flames

10.5. Incompatible materials
Strong oxidizing agents
Strong acids

10.6. Hazardous decomposition products

Substance	Condition
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:
Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. May cause additional health effects (see below).

Skin Contact:
Contact with the skin during product use is not expected to result in significant irritation.

Eye Contact:
Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion:
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Additional Health Effects:

Single exposure may cause target organ effects:
Cardiac Sensitization: Signs/symptoms may include irregular heartbeat (arrhythmia), faintness, chest pain, and may be fatal.

Toxicological Data
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Inhalation-Dust/Mist(4 hr)		No data available; calculated ATE >12.5 mg/l
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
White Mineral Oil (Petroleum)	Dermal	Rabbit	LD50 > 2,000 mg/kg
White Mineral Oil (Petroleum)	Ingestion	Rat	LD50 > 5,000 mg/kg

Isobutane	Inhalation-Gas (4 hours)	Rat	LC50 276,000 ppm
Sorbitan Oleate	Dermal		LD50 estimated to be > 5,000 mg/kg
Sorbitan Oleate	Ingestion	Rat	LD50 > 39,800 mg/kg
Ethanolamine	Inhalation-Vapor	official classification	LC50 estimated to be 10 - 20 mg/l
Ethanolamine	Dermal	Rabbit	LD50 1,000 mg/kg
Ethanolamine	Ingestion	Rat	LD50 1,720 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
White Mineral Oil (Petroleum)	Rabbit	No significant irritation
Isobutane	Professional judgement	No significant irritation
Ethanolamine	Rabbit	Corrosive

Serious Eye Damage/Irritation

Name	Species	Value
White Mineral Oil (Petroleum)	Rabbit	Mild irritant
Isobutane	Professional judgement	No significant irritation
Ethanolamine	Rabbit	Corrosive

Skin Sensitization

Name	Species	Value
White Mineral Oil (Petroleum)	Guinea pig	Not classified
Ethanolamine	Guinea pig	Not classified

Respiratory Sensitization

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
White Mineral Oil (Petroleum)	In Vitro	Not mutagenic
Isobutane	In Vitro	Not mutagenic
Ethanolamine	In Vitro	Not mutagenic
Ethanolamine	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
White Mineral Oil (Petroleum)	Dermal	Mouse	Not carcinogenic
White Mineral Oil (Petroleum)	Inhalation	Multiple animal species	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration

White Mineral Oil (Petroleum)	Ingestion	Not classified for female reproduction	Rat	NOAEL 4,350 mg/kg/day	13 weeks
White Mineral Oil (Petroleum)	Ingestion	Not classified for male reproduction	Rat	NOAEL 4,350 mg/kg/day	13 weeks
White Mineral Oil (Petroleum)	Ingestion	Not classified for development	Rat	NOAEL 4,350 mg/kg/day	during gestation
Ethanolamine	Dermal	Not classified for development	Rat	NOAEL 225 mg/kg/day	during organogenesis
Ethanolamine	Ingestion	Not classified for development	Rat	NOAEL 616 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Isobutane	Inhalation	cardiac sensitization	Causes damage to organs	Multiple animal species	NOAEL Not available	
Isobutane	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human and animal	NOAEL Not available	
Isobutane	Inhalation	respiratory irritation	Not classified	Mouse	NOAEL Not available	
Ethanolamine	Inhalation	respiratory irritation	May cause respiratory irritation	Human and animal	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
White Mineral Oil (Petroleum)	Ingestion	hematopoietic system	Not classified	Rat	NOAEL 1,381 mg/kg/day	90 days
White Mineral Oil (Petroleum)	Ingestion	liver | immune system	Not classified	Rat	NOAEL 1,336 mg/kg/day	90 days
Isobutane	Inhalation	kidney and/or bladder	Not classified	Rat	NOAEL 4,500 ppm	13 weeks
Ethanolamine	Inhalation	liver | kidney and/or bladder | respiratory system	Not classified	Multiple animal species	NOAEL 0.656 mg/l	5 weeks
Ethanolamine	Ingestion	hematopoietic system | liver | kidney and/or bladder | respiratory system	Not classified	Rat	NOAEL Not available	

Aspiration Hazard

Name	Value
White Mineral Oil (Petroleum)	Aspiration hazard

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

No data available.

SECTION 13: Disposal considerations

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Global inventory status

Contact 3M for more information. The components of this material are in compliance with the provisions of the Korea Chemical Control Act. Certain restrictions may apply. Contact the selling division for additional information. The components of this material are in compliance with the provisions of Australia National Industrial Chemical Notification and Assessment Scheme (NICNAS). Certain restrictions may apply. Contact the selling division for additional information. The components of this material are in compliance with the provisions of Japan Chemical Substance Control Law. Certain restrictions may apply. Contact the selling division for additional information. The components of this material are in compliance with the provisions of Philippines RA 6969 requirements. Certain restrictions may apply. Contact the selling division for additional information. The components of this product are in compliance with the new substance notification requirements of CEPA. The components of this product are in compliance with the chemical notification requirements of TSCA. This product complies with Measures on Environmental Management of New Chemical Substances. All ingredients are listed on or exempt from on China IECSC inventory.

Trade Secret Information:

HMIRA Registry Number:	Filing date:	Claim status:	Date of decision:
TBD		Claim for exemption has been filed.	

SECTION 16: Other information

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Health: 1 **Flammability:** 3 **Instability:** 0 **Special Hazards:** None
Aerosol Storage Code: 1

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

HMIS Hazard Classification

Health: 1 **Flammability:** 3 **Physical Hazard:** 0 **Personal Protection:** X - See PPE section.

Hazardous Material Identification System (HMIS® IV) hazard ratings are designed to inform employees of chemical hazards in the workplace. These ratings are based on the inherent properties of the material under expected conditions of normal use and are not intended for use in emergency situations. HMIS® IV ratings are to be used with a fully implemented HMIS® IV program. HMIS® is a registered mark of the American Coatings Association (ACA).

3M™ Stainless Steel Cleaner & Polish

Document group:	10-2819-0	**Version number:**	14.00
Issue Date:	2017/10/04	**Supercedes Date:**	2017/04/07

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3M Canada SDSs are available at www.3M.ca

SAFETY DATA SHEET

Confirms to OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

Product: Stainless Steel Cleaner and Polish- 02, 49, 102 **Revision Date:** 11-Mar-2015

SECTION 1 – IDENTIFICATION

Product Identifier

Product Name: **Stainless Steel Cleaner and Polish**

Product Code: **02, 49, 102**

Recommended Use of the Chemical and Restrictions for Use

Recommended Use: Cleaner

Restrictions for Use: Use only as directed.

Details of the Supplier

Manufacturer: Weiman Products
755 Tri-State Parkway
Gurnee, IL 60031
847-263-3500

Emergency Phone Number

24-Hour Number: 1-800-535-5053

International: 1-352-323-3500

SECTION 2 – HAZARDS IDENTIFICATION

Classification

Hazard Class	Category
Flammable aerosol	2
Gases under pressure- Liquefied gas	N/A

Label Elements

Hazard Symbols(s):

Signal Word(s): Warning

Hazard Statement(s): Flammable aerosol. Contains gas under pressure; may explode if heated.

Precautionary Statement(s): Keep away from heat/sparks/open flames/hot surfaces.-No smoking. Do not spray on an open flame or other ignition source. Pressurized container: Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50ºC/122ºF. Store in well-ventilated place.

Other Hazards

1% of the mixture consists of ingredients of unknown acute toxicity.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Wt %
Petroleum gases, liquefied	68476-85-7	10-30
Petroleum distillates, hydrotreated light	64742-47-8	7-13
White mineral oil, petroleum	8042-47-5	7-13

The exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

SECTION 4 – FIRST AID MEASURES

First Aid Measures

Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

Eye Contact: In case of contact, immediately flush eyes with plenty of water. Remove contact lenses, if worn. If irritation persists, get medical attention.

Ingestion: If swallowed, do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

Skin: If irritation occurs, flush skin with plenty of water. Get medical attention if irritation persists.

Most Important Symptoms and Effects (Acute and Delayed)

Inhalation: May cause respiratory tract irritation.

Eye Contact: May cause eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with possible redness and swelling.

Ingestion: May be harmful if swallowed. May cause stomach distress, nausea or vomiting.

Skin: May cause skin irritation. Symptoms may include redness, drying, defatting and cracking of the skin.

Indication of any Immediate Medical Attention and Special Treatment Needed

Note to Physician: Treat symptomatically.

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media

Suitable: Treat for surrounding material.

Unsuitable: None known.

Specific Hazards Arising from Chemical

Flammable aerosol. Products of combustion include, and are not limited to: oxides of carbon. Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns and injuries.

Protective Equipment and Precautions for Firefighters

Cool closed containers exposed to fire with water spray. Keep upwind of fire. Wear full fire-fighting turn-out gear (full Bunker gear) and respiratory protection (SCBA).

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures

Personal Precautions: Use personal protection recommended in Section 8. Isolate the hazard area and deny entry to unnecessary and unprotected personnel.

Environmental Precautions: See Section 12 for ecological information.

Methods and Material for Containment and Cleaning Up

Eliminated sources of ignition. Contain and/or absorb spill with inert material (e.g. sand, vermiculite), then place in a suitable container. Do not flush to sewer or allow to enter waterways. Use appropriate Personal Protective Equipment (PPE). Scoop up material and place in a disposal container. Provide ventilation.

SECTION 7 – HANDLING AND STORAGE

Precautions for Safe Handling

Handling: Keep away from sources of ignition- No smoking. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not swallow. When using do not eat, drink or smoke. Do not spray on an open flame or other ignition source. Pressurized container: Do not pierce or burn, even after use.

General Hygiene Advice: Launder contaminated clothing before use. Wash hands before eating, drinking, or smoking.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Proper grounding procedures to avoid static electricity should be followed. Keep out of the reach of children. Do not expose to temperatures exceeding 50ºC/122ºF. Store away from direct sunlight or other heat sources. Store in a well-ventilated place.

Incompatible Materials: Strong oxidizing agents.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Exposure Guidelines:

SAFETY DATA SHEET

Confirms to OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

Product: Stainless Steel Cleaner and Polish- 02, 49, 102 **Revision Date:** 11-Mar-2015

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Petroleum gases, liquefied (68476-85-7)	1000 ppm	180 mg/m^3	Not available
Petroleum distillates, hydrotreated light (64742-47-8)	Not available	Not available	Not available
White mineral oil, petroleum (8042-47-5)	Not available	Not available	Not available

Appropriate Engineering Controls

Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapor, etc.) below recommended exposure limits.

Individual Protection Measures

Respiratory Protection: In case of insufficient ventilation, wear suitable respiratory equipment. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Skin and Body Protection: Wear suitable protective clothing.

Eye/Face Protection: Safety glasses or goggles are recommended when using product.

General Work/Hygienic Practices: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White emulsion

Odor: Floral

Odor threshold: Not determined

pH: Not determined

Melting point/freezing point: Not determined

Initial boiling point and boiling range: Not determined

Flash point: >93.3ºC (>200ºF) TCC (concentrated product)

Evaporation rate: Not determined

Flammability (solid, gas): Flammable aerosol

Upper/lower flammability or explosive limits: Not determined

Vapor pressure: Not determined

Vapor density: Not determined

Relative density: 0.94

Solubility(ies): Not determined

Partition coefficient (n-octanol/water): Not determined

Auto-ignition temperature: Not determined

Decomposition temperature: Not determined

Viscosity: 2900-5600 cP at 25ºC (77ºF)

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions.

Chemical stability: Stable under recommended storage conditions. Flammable aerosol. Contents under pressure. Container may explode if heated. Do not puncture. Do not burn.

Possibility of hazardous reactions: None under normal use.

Conditions to avoid: Heat. Incompatible materials. Sources of ignition.

Incompatible materials: Strong oxidizing agents.

Hazardous decomposition products: May include and are not limited to: oxides of carbon.

SECTION 11 - TOXICOLOGICAL INFORMATION

SAFETY DATA SHEET

Confirms to OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

Product: Stainless Steel Cleaner and Polish- 02, 49, 102 **Revision Date:** 11-Mar-2015

Information on Toxicological Effects

Likely Routes of Exposure: Inhalation, skin contact, eye contact, ingestion

Information Related to Physical, Chemical, and Toxicological Effects

See section 4 of this SDS.

Delayed and Immediate Effects as well as Chronic Effects from Short and Long-term Exposure

Carcinogenicity: **NTP:** No **IARC:** No **OSHA:** No

Numerical Measures of Toxicity

Product	
ATE (oral)	>2000 mg/kg, rat
ATE (dermal)	>2000 mg/kg, rabbit
ATE (inhalation)	>5 mg/l/4h, rat

Component Information:

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Petroleum gases, liquefied (68476-85-7)	Not available	Not available	658 mg/l/4h (rat)
Petroleum distillates, hydrotreated light (64742-47-8)	>5000 mg/kg (rat)	>2000 mg/kg (rabbit)	>5.2 mg/l/4h (rat)
White mineral oil, petroleum (8042-47-5)	>5000 mg/kg (rat)	>2000 mg/kg (rabbit)	>5 mg/l/4h (rat)

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity: Not established

Persistence and degradability: Not established

Bioaccumulative potential: Not established

Mobility in soil: Not established

Other adverse effects: No additional information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

See section 8 of this SDS for exposure controls and personal protection.

Dispose of the product and container in accordance with all applicable local, state, and federal regulations.

SECTION 14 – TRANSPORT INFORMATION

Note: Classification changes based on quantity, packaging, and method of shipment. See current shipping paper for most up to date shipping information.

UN1950, Aerosols, 2.1

DOT (Ground): Limited quantity

IATA (Air): Regulated

IMDG (Vessel): Limited quantity

SECTION 15 – REGULATORY INFORMATION

All ingredients in this product are listed or are excluded from listing on the US Toxic Substances Act (TSCA) Chemical Substance Inventory.

This product is labeled in accordance with regulations administered by the Consumer Product Safety Commission (CPSC). The use pattern and exposure in the workplace are generally not consistent with those experienced by consumers. The requirements of the Occupational Safety and Health Administration (OSHA) applicable to this Safety Data Sheet differ from the requirements of the CPSC and as a result, this SDS may contain additional health hazard information not pertinent to consumer use and not found on the product label.

SECTION 16 – OTHER INFORMATION

Issue Date: 11-Mar-2015

Revision Date: 11-Mar-2015

SAFETY DATA SHEET

Confirms to OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

Product: Stainless Steel Cleaner and Polish- 02, 49, 102 **Revision Date:** 11-Mar-2015

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designed and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 81906-75 Rev. AG
Revised (year/month/day) 2015/03/18

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name SUBSTRATE

Part Number 81906

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Fluorescent yellow; Translucent; Liquid; Slight amine odor

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

2-Amino-2-methyl-1-propanol

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.
Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
2-Amino-2-methyl-1-propanol CAS # 124-68-5 EINECS # 204-709-8 Index # 603-070-00-6	< 10	Xi;R36/38 R52/53	Aquatic Longterm 3 Eye Irrit. 2 Skin Irrit. 2 H315; H319; H412	Acute Tox. Dermal 5 Acute Tox. Oral 5 Aquatic Longterm 3 Eye Irrit. 2 Skin Irrit. 2 H303; H313; H315; H319; H412	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

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Section 4 First Aid Measures (Continued)

Skin Contact — In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

Causes mild skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Wear protective gloves, protective clothing and eye/face protection.

Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions — Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures — As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections — Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

DFG MAK

2-Amino-2-methyl-1-propanol
CAS # 124-68-5

Ireland None established

IOELVs None established

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.01 @20°C

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Section 9 Physical and Chemical Properties (Continued)

Color	Fluorescent yellow	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Slight amine odor	**Organic**	Not determined
pH	9.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

2-Amino-2-methyl-1-propanol
CAS # 124-68-5 — Oral LD50 Rat 2900 mg/kg; Dermal LD50 Rabbit >2000 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	
2-Amino-2-methyl-1-propanol CAS # 124-68-5	96 h LC50 Lepomis macrochirus: 190 mg/L [static]
Microtox	No information available.
Water Flea	
2-Amino-2-methyl-1-propanol CAS # 124-68-5	48 h EC50 Daphnia magna: 193 mg/L
Fresh Water Algae	
2-Amino-2-methyl-1-propanol CAS # 124-68-5	72 h EC50 Desmodesmus subspicatus: 520 mg/L

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

No ingredients listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

2-Amino-2-methyl-1-propanol is listed.

New Jersey Dept. of Health RTK List

2-Amino-2-methyl-1-propanol is listed.

Pennsylvania RTK

2-Amino-2-methyl-1-propanol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 15 Regulatory Information (Continued)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Xi - Irritant
R36/38 Irritating to eyes and skin.
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 3 - Aquatic Hazard Long term, Category 3
Skin Irrit. 2 - Skin Irritation Category 2
H303 - May be harmful if swallowed
H313 - May be harmful In contact with skin
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H412 - Harmful to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - Internal Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: 657365-75: Rev. AJ
Revised (year/month/day) 2015/05/22

Product Information

Product Name	SYNCHRON Control Multilevel Comprehensive Chemistry Control Serum
Part Number	657365
Series Name	SYNCHRON Systems

Components

Description	Comprehensive Chemistry Control Serum (Human Origin) **Level 1** Comprehensive Chemistry Control Serum (Human Origin) **Level 2** Comprehensive Chemistry Control Serum (Human Origin) **Level 3**

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 657365-75 Rev. AJ
Revised (year/month/day) 2015/05/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Comprehensive Chemistry Control Serum (Human Origin)
Level 1

Part Number Component of P/N 657365

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Amber; Translucent; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Acute Toxicity Oral, Category 4

Classification according to EC Directives 1999/45/EC and 67/548/EEC

R22

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Acute Toxicity Oral, Category 4

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethylene Glycol

Pictogram

Signal Word

WARNING

Hazard Statements

H302 Harmful if swallowed.

Precautionary Statements

P264 Wash hands thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethylene Glycol CAS # 107-21-1 EINECS # 203-473-3 Index # 603-027-00-1	30 - 40	Xn;R 22	Acute Tox. Oral 4 H302	Acute Tox. Oral 4 H302	
Methanol CAS # 67-56-1 EINECS # 200-659-6 Index # 603-001-00-X	< 0.1	F;R11 T;R23/24/25- 39/23/24/25	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful if swallowed.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at -20 to -15°C , as directed on the product label. Keep container closed.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA

ACGIH

Methanol CAS # 67-56-1	250 ppm STEL; 200 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
Ethylene Glycol CAS # 107-21-1	100 mg/m3 Ceiling (aerosol only)

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Methanol CAS # 67-56-1	800 ppm Peak; 1080 mg/m3 Peak; skin notation; 200 ppm TWA MAK; 270 mg/m3 TWA MAK
Ethylene Glycol CAS # 107-21-1	20 ppm Peak; 52 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 26 mg/m3 TWA MAK

Ireland

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA; Potential for cutaneous absorption
Ethylene Glycol CAS # 107-21-1	10 mg/m3 TWA (particulate); 20 ppm TWA (vapour); 52 mg/m3 TWA (vapour); 40 ppm STEL (vapour); 104 mg/m3 STEL (vapour); Potential for cutaneous absorption

IOELVs

Methanol CAS # 67-56-1	Possibility of significant uptake through the skin; 200 ppm TWA; 260 mg/m3 TWA
Ethylene Glycol CAS # 107-21-1	Possibility of significant uptake through the skin; 20 ppm TWA; 52 mg/m3 TWA; 40 ppm STEL; 104 mg/m3 STEL

NIOSH

Methanol CAS # 67-56-1	6000 ppm IDLH; 250 ppm STEL; 325 mg/m3 STEL; 200 ppm TWA; 260 mg/m3 TWA

Japan

Methanol CAS # 67-56-1	200 ppm OEL; 260 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.068 @20°C

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Section 9 Physical and Chemical Properties (Continued)

Color	Amber	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.4 - 8.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Methanol 160 ppm geometric mean air odor threshold = (detectable); 690 ppm geometric mean air odor threshold = (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Methanol CAS # 67-56-1	Inhalation LC50 Rat 83.2 mg/L 4 h; Inhalation LC50 Rat 64000 ppm 4 h; Oral LD50 Rat 5628 mg/kg; Dermal LD50 Rabbit 15800 mg/kg
Ethylene Glycol CAS # 107-21-1	Oral LD50 Rat 4000 mg/kg; Dermal LD50 Rabbit 9530 µL/kg

Primary Routes of Exposure
Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation
No data available.

Serious eye damage/eye irritation
No data available.

Respiratory/skin sensitization
No data available.

Carcinogenicity
This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity
No data available.

Reproductive Toxicity
No data available.

Specific target organ toxicity – single exposure
No data available.

Specific target organ toxicity – repeated exposure
No data available.

Aspiration hazard
No data available.

Other Information
May be harmful if swallowed.
This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Methanol CAS # 67-56-1	96 h LC50 Pimephales promelas: 28200 mg/L [flow-through]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 19500 - 20700 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 18 - 20 mL/L [static]; 96 h LC50 Lepomis macrochirus: 13500 - 17600 mg/L [flow-through]
Ethylene Glycol CAS # 107-21-1	96 h LC50 Oncorhynchus mykiss: 41000 mg/L; 96 h LC50 Oncorhynchus mykiss: 14 - 18 mL/L [static]; 96 h LC50 Lepomis macrochirus: 27540 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 40761 mg/L [static]; 96 h LC50

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Section 12 Ecological Information (Continued)

		Pimephales promelas: 40000 - 60000 mg/L [static]; 96 h LC50 Poecilia reticulata: 16000 mg/L [static]
	Microtox	No information available.
	Water Flea	
	Ethylene Glycol CAS # 107-21-1	48 h EC50 Daphnia magna: 46300 mg/L
	Fresh Water Algae	
	Ethylene Glycol CAS # 107-21-1	96 h EC50 Pseudokirchneriella subcapitata: 6500 - 13000 mg/L
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Glycol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Methanol is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

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Section 15 Regulatory Information (Continued)

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Tobramycin has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.
Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.

S37/39 Wear suitable gloves and eye/face protection.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Methanol
Acetaldehyde
Ethylene Oxide
Ethylene Glycol
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes None

Hazard Class, hazard statements and risk phrase description from section 3

F - Highly flammable
T - Toxic
Xn - Harmful
R 22 Harmful if swallowed.
R11 Highly flammable.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

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Section 16 Other Information (Continued)

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Flam. Liq. 2 - Flammable Liquids, Category 2
STOT SE 1 - Specific Target Organ Toxicity Single Exposure Category 1
H225 - Highly flammable liquid and vapour.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H331 - Toxic if inhaled.
H370 - Causes damage to organs.
H370 - Causes damage to organs (Respiratory system)
H370 - Causes damage to organs (Liver and Kidney)
H370 - Causes damage to organs (Kidney)
H370 - Causes damage to organs (Liver)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Section 16 Other Information (Continued)

EC50 - Effective Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 657365-75 Rev. AJ
Revised (year/month/day) 2015/05/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Comprehensive Chemistry Control Serum (Human Origin) **Level 2**

Part Number Component of P/N 657365

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Amber; Translucent; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Acute Toxicity Oral, Category 4

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Acute Toxicity Oral, Category 4

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethylene Glycol
γ-Glutamyltransferase

Pictogram

Signal Word

WARNING

Hazard Statements

H302 Harmful if swallowed.

EUH208 May produce an allergic reaction.

Precautionary Statements

P264 Wash hands thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

1.9% of product contains ingredients of unknown oral toxicity.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethylene Glycol CAS # 107-21-1 EINECS # 203-473-3 Index # 603-027-00-1	30 - 40	Xn;R 22	Acute Tox. Oral 4 H302	Acute Tox. Oral 4 H302	

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Section 3 Composition and Information on Ingredients (Continued)

Methanol CAS # 67-56-1 EINECS # 200-659-6 Index # 603-001-00-X	< 0.1	F;R11 T;R23/24/25- 39/23/24/25	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	2, 8
γ-Glutamyltransferase CAS # 9046-27-9 EINECS # 232-931-5 Index # Not available	< 0.1	No	Resp. Sens. 1 H334	Resp. Sens. 1 H334	15, 8

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful if swallowed.

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

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Section 5 Fire Fighting Measures (Continued)

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at -20 to -15°C , as directed on the product label. Keep container closed.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA

ACGIH

Methanol CAS # 67-56-1	250 ppm STEL; 200 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
Ethylene Glycol CAS # 107-21-1	100 mg/m3 Ceiling (aerosol only)

DFG MAK

Methanol CAS # 67-56-1	800 ppm Peak; 1080 mg/m3 Peak; skin notation; 200 ppm TWA MAK; 270 mg/m3 TWA MAK
Ethylene Glycol CAS # 107-21-1	20 ppm Peak; 52 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 26 mg/m3 TWA MAK

Ireland

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA; Potential for cutaneous absorption
Ethylene Glycol CAS # 107-21-1	10 mg/m3 TWA (particulate); 20 ppm TWA (vapour); 52 mg/m3 TWA (vapour); 40 ppm STEL (vapour); 104 mg/m3 STEL (vapour); Potential for cutaneous absorption

IOELVs

Methanol CAS # 67-56-1	Possibility of significant uptake through the skin; 200 ppm TWA; 260 mg/m3 TWA
Ethylene Glycol CAS # 107-21-1	Possibility of significant uptake through the skin; 20 ppm TWA; 52 mg/m3 TWA; 40 ppm STEL; 104 mg/m3 STEL

NIOSH

Methanol CAS # 67-56-1	6000 ppm IDLH; 250 ppm STEL; 325 mg/m3 STEL; 200 ppm TWA; 260 mg/m3 TWA

Japan

Methanol CAS # 67-56-1	200 ppm OEL; 260 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.068 @20°C
Color	Amber	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.4 - 8.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Methanol 160 ppm geometric mean air odor threshold = (detectable); 690 ppm geometric mean air odor threshold = (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Methanol CAS # 67-56-1	Inhalation LC50 Rat 83.2 mg/L 4 h; Inhalation LC50 Rat 64000 ppm 4 h; Oral LD50 Rat 5628 mg/kg; Dermal LD50 Rabbit 15800 mg/kg
Ethylene Glycol CAS # 107-21-1	Oral LD50 Rat 4000 mg/kg; Dermal LD50 Rabbit 9530 µL/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity

This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

May be harmful if swallowed.

This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Methanol CAS # 67-56-1	96 h LC50 Pimephales promelas: 28200 mg/L [flow-through]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 19500 - 20700 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 18 - 20 mL/L [static]; 96 h LC50 Lepomis macrochirus: 13500 - 17600 mg/L [flow-through]
Ethylene Glycol CAS # 107-21-1	96 h LC50 Oncorhynchus mykiss: 41000 mg/L; 96 h LC50 Oncorhynchus mykiss: 14 - 18 mL/L [static]; 96 h LC50 Lepomis macrochirus: 27540 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 40761 mg/L [static]; 96 h LC50 Pimephales promelas: 40000 - 60000 mg/L [static]; 96 h LC50 Poecilia reticulata: 16000 mg/L [static]

Microtox No information available.

Water Flea

Ethylene Glycol CAS # 107-21-1	48 h EC50 Daphnia magna: 46300 mg/L

Fresh Water Algae

Ethylene Glycol CAS # 107-21-1	96 h EC50 Pseudokirchneriella subcapitata: 6500 - 13000 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Glycol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Methanol is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Tobramycin has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.
Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
S37/39 Wear suitable gloves and eye/face protection.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Methanol
Acetaldehyde
Ethylene Oxide
Ethylene Glycol
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 2.

Hazard Class, hazard statements and risk phrase description from section 3

F - Highly flammable
T - Toxic
Xn - Harmful
R 22 Harmful if swallowed.
R11 Highly flammable.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Flam. Liq. 2 - Flammable Liquids, Category 2
Resp. Sens. 1 - Respiratory Sensitization Category 1
STOT SE 1 - Specific Target Organ Toxicity Single Exposure Category 1
H225 - Highly flammable liquid and vapour.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H370 - Causes damage to organs.
H370 - Causes damage to organs (Respiratory system)
H370 - Causes damage to organs (Liver and Kidney)
H370 - Causes damage to organs (Kidney)
H370 - Causes damage to organs (Liver)

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 657365-75 Rev. AJ
Revised (year/month/day) 2015/05/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Comprehensive Chemistry Control Serum (Human Origin) **Level 3**

Part Number Component of P/N 657365

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

For full text of R- phrases: see Section 16.

Amber; Translucent; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Acute Toxicity Oral, Category 4

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Acute Toxicity Oral, Category 4

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethylene Glycol
γ-Glutamyltransferase

Pictogram

Signal Word

WARNING

Hazard Statements

H302 Harmful if swallowed.

EUH208 May produce an allergic reaction.

Precautionary Statements

P264 Wash hands thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.2.5% of product contains ingredients of unknown oral toxicity.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethylene Glycol CAS # 107-21-1 EINECS # 203-473-3 Index # 603-027-00-1	30 - 40	Xn;R 22	Acute Tox. Oral 4 H302	Acute Tox. Oral 4 H302	

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Global SDS – English

Section 3 Composition and Information on Ingredients (Continued)

Methanol CAS # 67-56-1 EINECS # 200-659-6 Index # 603-001-00-X	< 0.1	F;R11 T;R23/24/25- 39/23/24/25	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	2, 8
γ-Glutamyltransferase CAS # 9046-27-9 EINECS # 232-931-5 Index # Not available	< 0.1	No	Resp. Sens. 1 H334	Resp. Sens. 1 H334	15, 8

15 - May produce an allergic reaction.
2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful if swallowed.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at -20 to -15°C , as directed on the product label. Keep container closed.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA

ACGIH

Methanol CAS # 67-56-1	250 ppm STEL; 200 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
Ethylene Glycol CAS # 107-21-1	100 mg/m3 Ceiling (aerosol only)

DFG MAK

Methanol CAS # 67-56-1	800 ppm Peak; 1080 mg/m3 Peak; skin notation; 200 ppm TWA MAK; 270 mg/m3 TWA MAK
Ethylene Glycol CAS # 107-21-1	20 ppm Peak; 52 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 26 mg/m3 TWA MAK

Ireland

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA; Potential for cutaneous absorption
Ethylene Glycol CAS # 107-21-1	10 mg/m3 TWA (particulate); 20 ppm TWA (vapour); 52 mg/m3 TWA (vapour); 40 ppm STEL (vapour); 104 mg/m3 STEL (vapour); Potential for cutaneous absorption

IOELVs

Methanol CAS # 67-56-1	Possibility of significant uptake through the skin; 200 ppm TWA; 260 mg/m3 TWA
Ethylene Glycol CAS # 107-21-1	Possibility of significant uptake through the skin; 20 ppm TWA; 52 mg/m3 TWA; 40 ppm STEL; 104 mg/m3 STEL

NIOSH

Methanol CAS # 67-56-1	6000 ppm IDLH; 250 ppm STEL; 325 mg/m3 STEL; 200 ppm TWA; 260 mg/m3 TWA

Japan

Methanol CAS # 67-56-1	200 ppm OEL; 260 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.068 @20°C
Color	Amber	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Odorless	**Organic**	Not applicable
pH	8.4 - 8.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Methanol 160 ppm geometric mean air odor threshold = (detectable); 690 ppm geometric mean air odor threshold = (recognizable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Methanol CAS # 67-56-1	Inhalation LC50 Rat 83.2 mg/L 4 h; Inhalation LC50 Rat 64000 ppm 4 h; Oral LD50 Rat 5628 mg/kg; Dermal LD50 Rabbit 15800 mg/kg
Ethylene Glycol CAS # 107-21-1	Oral LD50 Rat 4000 mg/kg; Dermal LD50 Rabbit 9530 µL/kg

Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

May be harmful if swallowed.

This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Methanol CAS # 67-56-1	96 h LC50 Pimephales promelas: 28200 mg/L [flow-through]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 19500 - 20700 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 18 - 20 mL/L [static]; 96 h LC50 Lepomis macrochirus: 13500 - 17600 mg/L [flow-through]
Ethylene Glycol CAS # 107-21-1	96 h LC50 Oncorhynchus mykiss: 41000 mg/L; 96 h LC50 Oncorhynchus mykiss: 14 - 18 mL/L [static]; 96 h LC50 Lepomis macrochirus: 27540 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 40761 mg/L [static]; 96 h LC50 Pimephales promelas: 40000 - 60000 mg/L [static]; 96 h LC50 Poecilia reticulata: 16000 mg/L [static]

Microtox — No information available.

Water Flea

Ethylene Glycol CAS # 107-21-1	48 h EC50 Daphnia magna: 46300 mg/L

Fresh Water Algae

Ethylene Glycol CAS # 107-21-1	96 h EC50 Pseudokirchneriella subcapitata: 6500 - 13000 mg/L

12.2 Persistence and degradability — Not determined for the product.

12.3 Bioaccumulation — Not determined for the product.

12.4 Mobility in soil — Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects — No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Glycol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Methanol is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Tobramycin has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.
Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Phenytoin (PHY) is listed.
Methanol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Digoxin is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
S37/39 Wear suitable gloves and eye/face protection.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Methanol
Acetaldehyde
Ethylene Oxide
Ethylene Glycol
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated Section 2.

Hazard Class, hazard statements and risk phrase description from section 3

F - Highly flammable
T - Toxic
Xn - Harmful
R 22 Harmful if swallowed.
R11 Highly flammable.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Flam. Liq. 2 - Flammable Liquids, Category 2
Resp. Sens. 1 - Respiratory Sensitization Category 1
STOT SE 1 - Specific Target Organ Toxicity Single Exposure Category 1
H225 - Highly flammable liquid and vapour.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H370 - Causes damage to organs.
H370 - Causes damage to organs (Respiratory system)
H370 - Causes damage to organs (Liver and Kidney)
H370 - Causes damage to organs (Kidney)
H370 - Causes damage to organs (Liver)

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 442600-75 Rev. AJ
Revised (year/month/day) 2015/05/08

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name SYNCHRON® Multi Calibrator

Part Number 442600

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Amber; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Acute Toxicity Oral, Category 4

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xn;R22

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Acute Toxicity Oral, Category 4

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethylene Glycol

Pictogram

Signal Word

WARNING

Hazard Statements

H302 Harmful if swallowed.

Precautionary Statements

P264 Wash hands thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethylene Glycol CAS # 107-21-1 EINECS # 203-473-3 Index # 603-027-00-1	30 - 40	Xn;R 22	Acute Tox. Oral 4 H302	Acute Tox. Oral 4 H302	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at -20 to -15°C , as directed on the product label. Keep container closed.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Ethylene Glycol CAS # 107-21-1	100 mg/m3 Ceiling (aerosol only)

DFG MAK

Ethylene Glycol CAS # 107-21-1	20 ppm Peak; 52 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 26 mg/m3 TWA MAK

Ireland

Ethylene Glycol CAS # 107-21-1	10 mg/m3 TWA (particulate); 20 ppm TWA (vapour); 52 mg/m3 TWA (vapour); 40 ppm STEL (vapour); 104 mg/m3 STEL (vapour); Potential for cutaneous absorption

IOELVs

Ethylene Glycol CAS # 107-21-1	Possibility of significant uptake through the skin; 20 ppm TWA; 52 mg/m3 TWA; 40 ppm STEL; 104 mg/m3 STEL

NIOSH

None established

Japan

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈1.065 @20°C
Color	Amber	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.4-8.6	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.2 Chemical Stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid — To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Ethylene Glycol CAS # 107-21-1	Oral LD50 Rat 4000 mg/kg; Dermal LD50 Rabbit 9530 µL/kg

Primary Routes of Exposure — Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation — No data available.

Serious eye damage/eye irritation — No data available.

Respiratory/skin sensitization — No data available.

Carcinogenicity — This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity — No data available.

Reproductive Toxicity — No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — Harmful if swallowed.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Ethylene Glycol CAS # 107-21-1	96 h LC50 Oncorhynchus mykiss: 41000 mg/L; 96 h LC50 Oncorhynchus mykiss: 14 - 18 mL/L [static]; 96 h LC50 Lepomis macrochirus: 27540 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 40761 mg/L [static]; 96 h LC50 Pimephales promelas: 40000 - 60000 mg/L [static]; 96 h LC50 Poecilia reticulata: 16000 mg/L [static]
Microtox	No information available.

Water Flea

Ethylene Glycol CAS # 107-21-1	48 h EC50 Daphnia magna: 46300 mg/L

Fresh Water Algae

Ethylene Glycol CAS # 107-21-1	96 h EC50 Pseudokirchneriella subcapitata: 6500 - 13000 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Glycol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Glycerol is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

New Jersey Dept. of Health RTK List

Glycerol is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

Ethylene Glycol is listed.

1,4-Dioxane is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Glycerol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Harmful
Xn

Risk and Safety Phrases

R22 Harmful if swallowed.
S37/39 Wear suitable gloves and eye/face protection.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
Ethylene Glycol
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

Xn - Harmful
R 22 Harmful if swallowed.
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
H302 - Harmful if swallowed.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: A24510-75 Rev. AF
Revised (year/month/day) 2015/04/14

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name System Check HS

Part Number A24510

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For laboratory use only

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Light yellow to dark yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Eye Irritation Category 2
Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Eye Irritation Category 2

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Ethoxylated lauryl alcohol

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard Classification of Pure Ingredients

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Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Ethoxylated lauryl alcohol CAS # 9002-92-0 EINECS # Not available Index # Not available	1.0 - 2.8	Xn;R22-38-41	Acute Tox. Oral 4 Eye Dam. 1 Skin Irrit. 2 H302; H315; H318	Acute Tox. Oral 4 Eye Dam. 1 Skin Irrit. 2 H302; H315; H318	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

Causes mild skin irritation.

Causes serious eye irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

	Flammable Properties	Nonflammable aqueous solution.
5.1	**Extinguishing Media**	In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3	**Advice for fire fighters**	
	Protective Equipment	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions	This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures. Wear protective gloves, protective clothing and eye/face protection.
6.2 Environmental Precautions	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures	As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
6.4 Reference to other sections	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling	This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02
Color	Light yellow to dark yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes eye irritation
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

WHMIS Classification: D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Skin Irritation)
D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Eye Irritation)

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Ethoxylated lauryl alcohol
Sodium Azide

Ingredients with unknown toxicological properties

None

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
Xn - Harmful
R22 Harmful if swallowed.
R38 Irritating to skin.
R41 Risk of serious damage to eyes.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.

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Section 16 Other Information (Continued)

R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances

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Section 16 Other Information (Continued)

SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: 33560-75: Rev. AG
Revised (year/month/day) 2015/04/21

Product Information

Product Name	TESTOSTERONE
Part Number	33560
Series Name	ACCESS®

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Particle/Conjugate (Compartment R1a)
Sample Treatment Solution (Compartment R1b)
Antibody (Compartment R1c)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: 33560-75 Rev. AG
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Particle/Conjugate (Compartment R1a)

Part Number Component of P/N 33560

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0105 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6	**Partition coefficient: n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes skin irritation.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	Causes eye irritation
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Danazol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Danazol is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Sucrose is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33560-75 Rev. AG
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Sample Treatment Solution (Compartment R1b)

Part Number Component of P/N 33560

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Irritation Category 2
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 2
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Acetic Acid

Pictogram

Signal Word

DANGER

Hazard Statements

H315 Causes skin irritation.

H318 Causes serious eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Acetic Acid CAS # 64-19-7 EINECS # 200-580-7 Index # 607-002-00-6	< 5	C;R10-35	Flam. Liq. 3 Skin Corr. 1A H226; H314	Flam. Liq. 3 Skin Corr. 1A H226; H314	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye damage.
Causes skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.
Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA

ACGIH

Acetic Acid CAS # 64-19-7	15 ppm STEL; 10 ppm TWA
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Acetic Acid CAS # 64-19-7	20 ppm Peak; 50 mg/m3 Peak; 10 ppm TWA MAK; 25 mg/m3 TWA MAK
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

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Section 8 Exposure Controls and Personal Protection (Continued)

Ireland

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA; 15 ppm STEL; 37 mg/m3 STEL
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

Acetic Acid CAS # 64-19-7	50 ppm IDLH; 15 ppm STEL; 37 mg/m3 STEL; 10 ppm TWA; 25 mg/m3 TWA

Japan

Acetic Acid CAS # 64-19-7	10 ppm OEL; 25 mg/m3 OEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0258 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	4.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Acetic Acid 0.074 ppm geometric mean air odor threshold = (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Acetic Acid CAS # 64-19-7	Inhalation LC50 Rat 11.4 mg/L 4 h; Oral LD50 Rat 3310 mg/kg; Dermal LD50 Rabbit 1060 mg/kg
Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes serious eye damage.
Respiratory/skin sensitization	No data available.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	No data available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Acetic Acid CAS # 64-19-7	96 h LC50 Pimephales promelas: 79 mg/L [static]; 96 h LC50 Lepomis macrochirus: 75 mg/L [static]
Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.

Water Flea

Acetic Acid CAS # 64-19-7	24 h EC50 Daphnia magna: 47 mg/L; 48 h EC50 Daphnia magna: 65 mg/L [Static]
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetic Acid is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given

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Section 15 Regulatory Information (Continued)

to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetic Acid
Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
N - Dangerous for the environment
T+ - Very toxic
R10 Flammable.
R35 Causes severe burns.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Flam. Liq. 3 - Flammable Liquids, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
H226 - Flammable liquid and vapour.
H300 - Fatal if swallowed.
H314 - Causes severe skin burns and eye damage.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration

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Section 16 Other Information (Continued)

PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33560-75 Rev. AG
Revised (year/month/day) 2015/04/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Antibody (Compartment R1c)

Part Number Component of P/N 33560

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.1	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes eye irritation

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Section 11 Toxicological Information (Continued)

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Phosphate, Dibasic is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Phosphate, Dibasic is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

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Section 16 Other Information (Continued)

	Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 Skin Corr. 1B - Skin Corrosion Category 1B Skin Sens. 1 - Skin Sensitization Category 1 H300 - Fatal if swallowed. H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LC50 - Lethal Concentration, 50% LD50 - Lethal Dose, 50%

*ProClin is a trademark of the Rohm and Haas Company.

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6112-75: Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Product Information

Product Name	Total Bilirubin
Part Number	OSR6112, OSR6212, OSR6612

Components

Description	Total Bilirubin Blank R1 Total Bilirubin Color R1

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Document ID: OSR6112-75 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Total Bilirubin Blank R1

Part Number Component of P/N OSR6112, OSR6212, OSR6612

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Pungent

according to EC 1272/2008 (CLP/GHS)

Skin Irritation Category 2

Eye Damage Category 1

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 2
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Acetic Acid
Lithium dodecyl sulphate

Pictogram

Signal Word

DANGER

Hazard Statements

H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Lithium dodecyl sulphate CAS # 2044-56-6 EINECS # 218-058-2 Index # Not available	2 - 5	Eye Dam. 1, H318 Flam. Sol. 2, H228 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Dam. 1, H318 Flam. Sol. 2, H228 STOT SE 3, H335 Skin Irrit. 2, H315	

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Section 3 Composition and Information on Ingredients (Continued)

Lithium Acetate CAS # 546-89-4 EINECS # 208-914-3 Index # Not available	1 - 2	Acute Tox. Inhal. 4, H332 Acute Tox. Oral 4, H302	Acute Tox. Inhal. 4, H332 Acute Tox. Oral 4, H302	3, 8
Acetic Acid CAS # 64-19-7 EINECS # 200-580-7 Index # 607-002-00-6	0.1 - 1	Flam. Liq. 3, H226 Skin Corr. 1A, H314	Flam. Liq. 3, H226 Skin Corr. 1A, H314	

3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Contact may cause serious eye damage.

May cause skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Acetic Acid CAS # 64-19-7	15 ppm STEL; 10 ppm TWA

DFG MAK

Lithium Acetate CAS # 546-89-4	0.2 mg/m3 Peak (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (as Li) (inhalable fraction); 0.2 mg/m3 TWA MAK (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (inhalable fraction) (as Li)
Acetic Acid CAS # 64-19-7	20 ppm Peak; 50 mg/m3 Peak; 10 ppm TWA MAK; 25 mg/m3 TWA MAK
Lithium dodecyl sulphate CAS # 2044-56-6	0.2 mg/m3 Peak (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (inhalable fraction); 0.2 mg/m3 TWA MAK (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (inhalable fraction) (as Li)

Ireland

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA; 20 ppm STEL; 50 mg/m3 STEL

IOELVs

None established

NIOSH

Acetic Acid CAS # 64-19-7	50 ppm IDLH; 15 ppm STEL; 37 mg/m3 STEL; 10 ppm TWA; 25 mg/m3 TWA

Japan

Acetic Acid CAS # 64-19-7	10 ppm OEL; 25 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Lithium Acetate CAS # 546-89-4	0.02 mg/m3 Binding STEL
Acetic Acid CAS # 64-19-7	5 ppm TLV; 13 mg/m3 TLV; 10 ppm Binding STEL; 25 mg/m3 Binding STEL
Lithium dodecyl sulphate CAS # 2044-56-6	0.02 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.00049
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Pungent	**Organic**	Not determined
pH	4.2	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Acetic Acid 0.0004 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Acetic Acid CAS # 64-19-7	Dermal LD50 Rabbit 1060 mg/kg; Inhalation LC50 Rat 11.4 mg/L 4 h; Oral LD50 Rat 3310 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause skin irritation.
Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Acetic Acid CAS # 64-19-7	96 h LC50 Pimephales promelas: 79 mg/L [static]; 96 h LC50 Lepomis macrochirus: 75 mg/L [static]
Microtox	No information available.
Water Flea	
Acetic Acid CAS # 64-19-7	48 h EC50 Daphnia magna: 65 mg/L [Static]
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

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14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 64-19-7 Acetic Acid

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 64-19-7 Acetic Acid

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 64-19-7 Acetic Acid

Pennsylvania Right To Know (RTK) List

CAS # 64-19-7 Acetic Acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

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Section 15 Regulatory Information (Continued)

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated E-mail address in Sec. 1.3.
Updated Section 8, 11, 15, 16.
Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08
Document ID: OSR6112-75
Version: 07

Description of hazard Class and hazard statements from Section 3

Acute Tox. Inhal. 4 - Acute Toxicity Inhalation, Category 4
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Flam. Liq. 3 - Flammable Liquids, Category 3
Flam. Sol. 2 - Flammable Solids, Category 2
Skin Corr. 1A - Skin Corrosion Category 1A
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H226 - Flammable liquid and vapour.
H228 - Flammable solid.
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H332 - Harmful if inhaled.
H335 - May cause respiratory irritation.

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BECKMAN COULTER
Total Bilirubin
Total Bilirubin Blank R1

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

WHILE BECKMAN COULTER, INC. BELIEVES THE INFORMATION CONTAINED HEREIN IS VALID AND ACCURATE, BECKMAN COULTER, INC. MAKES NO WARRANTY OR REPRESENTATION AS TO ITS VALIDITY, ACCURACY, OR CURRENCY. BECKMAN COULTER, INC. SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR USE OF EITHER THIS INFORMATION OR MATERIALS TO WHICH IT APPLIES. DISPOSAL OF HAZARDOUS MATERIALS MAY BE SUBJECT TO LOCAL LAWS OR REGULATIONS.

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SAFETY DATA SHEET

Document ID: OSR6112-75 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Total Bilirubin Color R1

Part Number Component of P/N OSR6112, OSR6212, OSR6612

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow; Clear; Liquid; Pungent

according to EC 1272/2008 (CLP/GHS)

Skin Irritation Category 2

Eye Damage Category 1

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Total Bilirubin
Total Bilirubin Color R1

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 2
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Acetic Acid
Lithium dodecyl sulphate

Pictogram

Signal Word

DANGER

Hazard Statements

H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Lithium dodecyl sulphate CAS # 2044-56-6 EINECS # 218-058-2 Index # Not available	2 - 5	Eye Dam. 1, H318 Flam. Sol. 2, H228 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Dam. 1, H318 Flam. Sol. 2, H228 STOT SE 3, H335 Skin Irrit. 2, H315	

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Section 3 Composition and Information on Ingredients (Continued)

Lithium Acetate CAS # 546-89-4 EINECS # 208-914-3 Index # Not available	1 - 2	Acute Tox. Inhal. 4, H332 Acute Tox. Oral 4, H302	Acute Tox. Inhal. 4, H332 Acute Tox. Oral 4, H302	3, 8
Acetic Acid CAS # 64-19-7 EINECS # 200-580-7 Index # 607-002-00-6	0.1 - 1	Flam. Liq. 3, H226 Skin Corr. 1A, H314	Flam. Liq. 3, H226 Skin Corr. 1A, H314	

3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Contact may cause serious eye damage.
May cause skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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BECKMAN COULTER
Total Bilirubin
Total Bilirubin Color R1

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Acetic Acid CAS # 64-19-7	15 ppm STEL; 10 ppm TWA

DFG MAK

Lithium Acetate CAS # 546-89-4	0.2 mg/m3 Peak (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (as Li) (inhalable fraction); 0.2 mg/m3 TWA MAK (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (inhalable fraction) (as Li)
Acetic Acid CAS # 64-19-7	20 ppm Peak; 50 mg/m3 Peak; 10 ppm TWA MAK; 25 mg/m3 TWA MAK
Lithium dodecyl sulphate CAS # 2044-56-6	0.2 mg/m3 Peak (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (inhalable fraction); 0.2 mg/m3 TWA MAK (inorganic compounds, except Lithium and strong irritant Lithium compounds such as Lithium amide, Lithium hydride, Lithium hydroxide, Lithium nitride, Lithium oxide, Lithium tetrahydro aluminate, Lithium tetrahydroborate) (inhalable fraction) (as Li)

Ireland

Acetic Acid CAS # 64-19-7	10 ppm TWA; 25 mg/m3 TWA; 20 ppm STEL; 50 mg/m3 STEL

IOELVs None established

NIOSH

Acetic Acid CAS # 64-19-7	50 ppm IDLH; 15 ppm STEL; 37 mg/m3 STEL; 10 ppm TWA; 25 mg/m3 TWA

Japan

Acetic Acid CAS # 64-19-7	10 ppm OEL; 25 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Lithium Acetate CAS # 546-89-4	0.02 mg/m3 Binding STEL
Acetic Acid CAS # 64-19-7	5 ppm TLV; 13 mg/m3 TLV; 10 ppm Binding STEL; 25 mg/m3 Binding STEL
Lithium dodecyl sulphate CAS # 2044-56-6	0.02 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Pungent	**Organic**	Not determined
pH	4.2	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Acetic Acid 0.0004 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Acetic Acid CAS # 64-19-7	Dermal LD50 Rabbit 1060 mg/kg; Inhalation LC50 Rat 11.4 mg/L 4 h; Oral LD50 Rat 3310 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause skin irritation.
Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Acetic Acid CAS # 64-19-7	96 h LC50 Pimephales promelas: 79 mg/L [static]; 96 h LC50 Lepomis macrochirus: 75 mg/L [static]
Microtox	No information available.
Water Flea	
Acetic Acid CAS # 64-19-7	48 h EC50 Daphnia magna: 65 mg/L [Static]
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

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14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 64-19-7 Acetic Acid

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Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 64-19-7 Acetic Acid

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 64-19-7 Acetic Acid

Pennsylvania Right To Know (RTK) List

CAS # 64-19-7 Acetic Acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

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Section 15 Regulatory Information (Continued)

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated E-mail address in Sec. 1.3.
Updated Section 8, 11, 15, 16.
Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/05/08
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Description of hazard Class and hazard statements from Section 3

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Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
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Flam. Liq. 3 - Flammable Liquids, Category 3
Flam. Sol. 2 - Flammable Solids, Category 2
Skin Corr. 1A - Skin Corrosion Category 1A
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H226 - Flammable liquid and vapour.
H228 - Flammable solid.
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H332 - Harmful if inhaled.
H335 - May cause respiratory irritation.

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BECKMAN COULTER
Total Bilirubin
Total Bilirubin Color R1

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6132-75: Version 06
Revision Date (year/month/day) 2019/06/13
Last Revision Date (year/month/day) 2015/05/05

Product Information

Product Name	**Total Protein**
Part Number	OSR6132, OSR6232, OSR6632

Components

Description

Total Protein R1
Total Protein R2

Transport Information

Shipping Information	**IATA**	**IMDG**	**US DOT**	**European ADR**	**Canadian TDG**
UN/ID Number	1824	1824	1824	1824	1824
Shipping Name	Sodium hydroxide solution				
Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
Subsidiary Risk	None	None	None	None	None
Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
Packing Group	II	II	II	II	II
Special Provisions	A3	None	N34	None	None
Additional information					
IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	154	Not applicable	154
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

Warning: Corrosive substances.

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SAFETY DATA SHEET

Document ID: OSR6132-75 Version 06
Revision Date (year/month/day) 2019/06/13
Last Revision Date (year/month/day) 2015/05/05

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Total Protein R1

Part Number Component of P/N OSR6132, OSR6232, OSR6632

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

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Total Protein
Total Protein R1

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hydroxide

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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BECKMAN COULTER
Total Protein
Total Protein R1

Section 3 Composition and Information on Ingredients (Continued)

Sodium Hydroxide CAS # 1310-73-2 EINECS # 215-185-5 Index # 011-002-00-6	1 - 5	Eye Dam. 1, H318 Skin Corr. 1A, H314	Eye Dam. 1, H318 Skin Corr. 1A, H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

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BECKMAN COULTER
Total Protein
Total Protein R1

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sodium Hydroxide
CAS # 1310-73-2
2 mg/m3 TWA

ACGIH

Sodium Hydroxide
CAS # 1310-73-2
2 mg/m3 Ceiling

DFG MAK

None established

Ireland

Sodium Hydroxide
CAS # 1310-73-2
2 mg/m3 STEL

IOELVs

None established

NIOSH

Sodium Hydroxide
CAS # 1310-73-2
10 mg/m3 IDLH

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan	None established

Sweden (AFS 2015:7 and amendments)

Sodium Hydroxide CAS # 1310-73-2	1 mg/m3 TLV; 2 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	13 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Odor Threshold Not applicable

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hydroxide
CAS # 1310-73-2 Dermal LD50 Rabbit 1350 mg/kg; Oral LD50 Rat 140 - 340 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Contact may cause severe skin burns.

Serious eye damage/eye irritation Contact may cause serious eye damage.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hydroxide
CAS # 1310-73-2 — 96 h LC50 Oncorhynchus mykiss: 45.4 mg/L [static]

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

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Total Protein
Total Protein R1

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1824	1824	1824	1824	PIN - 1824
14.2	Shipping Name	Sodium hydroxide solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	Packing Group	II	II	II	II	II
	Special Provisions	A3	None	N34	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 1310-73-2 Sodium Hydroxide

California Proposition 65

Chemical which is known to the State of California to cause cancer

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 1310-73-2 Sodium Hydroxide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 1310-73-2 Sodium Hydroxide

Pennsylvania Right To Know (RTK) List

CAS # 1310-73-2 Sodium Hydroxide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1 Updated Section 4, 8, 11, 12, 15	

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Section 16 Other Information (Continued)

Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/06/13
Last Revision Date (year/month/day) 2015/05/05
Document ID: OSR6132-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Eye Dam. 1 - Eye Damage Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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SAFETY DATA SHEET

Document ID: OSR6132-75 Version 06
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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Total Protein R2

Part Number Component of P/N OSR6132, OSR6232, OSR6632

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Blue; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

Aquatic Hazard Long term, Category 3

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1
Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hydroxide
Copper sulphate

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.7.1% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:	Hazard	of Pure Ingredients

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Total Protein
Total Protein R2

Section 3 Composition and Information on Ingredients (Continued)

Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note
Copper sulphate CAS # 7758-98-7 EINECS # 231-847-6 Index # 029-004-00-0	0.5 - 1	Acute Tox. Oral 4, H302 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Irrit. 2, H319 Skin Irrit. 2, H315	Acute Tox. Oral 4, H302 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Irrit. 2, H319 Skin Irrit. 2, H315	
Sodium Hydroxide CAS # 1310-73-2 EINECS # 215-185-5 Index # 011-002-00-6	0.5 - 1	Eye Dam. 1, H318 Skin Corr. 1A, H314	Eye Dam. 1, H318 Skin Corr. 1A, H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 Ceiling

DFG MAK None established

Ireland

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 STEL

IOELVs None established

NIOSH

Sodium Hydroxide CAS # 1310-73-2	10 mg/m3 IDLH

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Hydroxide CAS # 1310-73-2	1 mg/m3 TLV; 2 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.05 @20°C
Color	Blue	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	13 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hydroxide CAS # 1310-73-2	Dermal LD50 Rabbit 1350 mg/kg; Oral LD50 Rat 140 - 340 mg/kg
Copper sulphate CAS # 7758-98-7	Dermal LD50 Rabbit 1000 mg/kg; Oral LD50 Rat 300 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Contact may cause severe skin burns.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hydroxide CAS # 1310-73-2	96 h LC50 Oncorhynchus mykiss: 45.4 mg/L [static]
Copper sulphate CAS # 7758-98-7	96 h LC50 Oncorhynchus mykiss: 0.1 mg/L
Microtox	No information available.

Water Flea

Copper sulphate CAS # 7758-98-7	48 h EC50 Daphnia magna: 0.0058 - 0.0073 mg/L [Static]
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Total Protein
Total Protein R2

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1824	1824	1824	1824	PIN - 1824
14.2	Shipping Name	Sodium hydroxide solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	Packing Group	II	II	II	II	II
	Special Provisions	A3	None	N34	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154

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BECKMAN COULTER
Total Protein
Total Protein R2

SAFETY DATA SHEET
Document ID: OSR6132-75 Version 06
Revision Date (year/month/day) 2019/06/13
Last Revision Date (year/month/day) 2015/05/05

Section 14 Transport Information (Continued)

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 1310-73-2	Sodium Hydroxide
CAS # 7758-98-7	Copper sulphate

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 1310-73-2	Sodium Hydroxide
CAS # 7758-98-7	Copper sulphate

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 1310-73-2	Sodium Hydroxide
CAS # 7758-98-7	Copper sulphate

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 1310-73-2	Sodium Hydroxide
CAS # 7758-98-7	Copper sulphate

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1
Updated Section 4, 8, 11, 12, 15
Updated Section 13.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/06/13
Last Revision Date (year/month/day) 2015/05/05
Document ID: OSR6132-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
Skin Irrit. 2 - Skin Irritation Category 2

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Total Protein
Total Protein R2

Section 16 Other Information (Continued)

H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Doc. ID: 33830-75: Rev. AK
Revised (year/month/day) 2015/03/18

Product Information

Product Name	Total T3
Part Number	33830
Series Name	ACCESS®

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

T3-ALP Conjugate/ Dynabeads® PMP (Compartment R1a)
T3-Biotin Conjugate (Compartment R1b)
0.4 N NaOH solution with ANS (Compartment R1c)
0.4 N HCl solution (Compartment R1d)

Transport Information

Shipping Information	**IATA**	**IMDG**	**US DOT**	**European ADR**	**Canadian TDG**
UN/ID Number	3316	3316	3316	3316	3316
Shipping Name	Chemical kit				
Hazard Class	9 Miscellaneous Dangerous Goods	9 Miscellaneous dangerous substances and articles	9 Miscellaneous hazardous material	9 Miscellaneous dangerous substances and articles	9 Miscellaneous Dangerous Goods
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	M11	Not applicable
Packing Group	II	II	II	II	II
Special Provisions	A44; A163; A802	251; 340	15	251	65
Additional information					
IATA ERG Code	9L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-P	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	171	Not applicable	171
Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

Warning: Corrosive substances.

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SAFETY DATA SHEET

Doc. ID: 33830-75 Rev. AK
Revised (year/month/day) 2015/03/18

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name T3-ALP Conjugate/ Dynabeads® PMP (Compartment R1a)

Part Number Component of P/N 33830

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Reddish-brown when particles suspended; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7	**Partition coefficient: n-octanol/water**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.

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Section 11 Toxicological Information (Continued)

Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause an allergic skin reaction.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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Global SDS – English

concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Zinc Chloride is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

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Section 16 Other Information (Continued)

	Skin Corr. 1B - Skin Corrosion Category 1B
	Skin Sens. 1 - Skin Sensitization Category 1
	H300 - Fatal if swallowed.
	H301 - Toxic if swallowed.
	H311 - Toxic in contact with skin.
	H314 - Causes severe skin burns and eye damage.
	H317 - May cause an allergic skin reaction.
	H331 - Toxic if inhaled.
	H400 - Very toxic to aquatic life.
	H410 - Very toxic to aquatic life with long lasting effects.
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Classification, Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA - International Air Transport Association
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LC50 - Lethal Concentration, 50%
	LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33830-75 Rev. AK
Revised (year/month/day) 2015/03/18

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name T3-Biotin Conjugate (Compartment R1b)

Part Number Component of P/N 33830

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.015 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.

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Section 11 Toxicological Information (Continued)

Respiratory/skin sensitization May cause an allergic skin reaction.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetonitrile is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetonitrile is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Zinc Chloride is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Acetonitrile is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetonitrile is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
Trifluoroacetic Acid is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetonitrile is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Zinc Chloride is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Global SDS – English

Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetonitrile
Acetaldehyde
Ethylene Oxide
Trifluoroacetic Acid
1,4-Dioxane
Zinc Chloride
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

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Section 16 Other Information (Continued)

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33830-75 Rev. AK
Revised (year/month/day) 2015/03/18

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name 0.4 N NaOH solution with ANS (Compartment R1c)

Part Number Component of P/N 33830

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Light yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R36/38

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hydroxide

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Hydroxide CAS # 1310-73-2 EINECS # 215-185-5 Index # 011-002-00-6	<2	C;R 35	Eye Dam. 1 Skin Corr. 1A H314; H318	Eye Dam. 1 Skin Corr. 1A H314; H318	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open and obtain medical attention immediately.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and tightly sealed eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 TWA

ACGIH

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 Ceiling

DFG MAK None established

Ireland

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 STEL

IOELVs None established

NIOSH

Sodium Hydroxide CAS # 1310-73-2	10 mg/m3 IDLH

Japan None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

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Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.015 @20°C
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	13	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hydroxide CAS # 1310-73-2	Dermal LD50 Rabbit 1350 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Causes severe skin burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hydroxide CAS # 1310-73-2	96 h LC50 Oncorhynchus mykiss: 45.4 mg/L [static]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1824	1824	1824	1824	PIN - 1824
14.2	Shipping Name	Sodium hydroxide solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	Packing Group	II	II	II	II	II
	Special Provisions	Not applicable	None	N34	None	None

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Section 14 Transport Information (Continued)

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
Additional information					
IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5 Environmental Hazards					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 Sodium Hydroxide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Hydroxide is listed.

New Jersey Dept. of Health RTK List

Sodium Hydroxide is listed.

Pennsylvania RTK Sodium Hydroxide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R36/38 Irritating to eyes and skin.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37/39 Wear suitable gloves and eye/face protection.

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Section 15 Regulatory Information (Continued)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1824

Ingredients on Ingredient Disclosure List

Sodium Hydroxide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 1** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
R 35 Causes severe burns.
Eye Dam. 1 - Eye Damage Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration

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Section 16 Other Information (Continued)

PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33830-75 Rev. AK
Revised (year/month/day) 2015/03/18

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name 0.4 N HCl solution (Compartment R1d)

Part Number Component of P/N 33830

Series Name ACCESS®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Hydrochloric Acid...%

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Hydrochloric Acid...% CAS # 7647-01-0 EINECS # 231-595-7 Index # 017-002-01-X	<4	C;R34-37	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open and obtain medical attention immediately.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and tightly sealed eye/face protection.

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Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Hydrochloric Acid...% CAS # 7647-01-0	5 ppm Ceiling; 7 mg/m3 Ceiling

ACGIH

Hydrochloric Acid...% CAS # 7647-01-0	2 ppm Ceiling

DFG MAK

Hydrochloric Acid...% CAS # 7647-01-0	4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

Ireland

Hydrochloric Acid...% CAS # 7647-01-0	5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

IOELVs

Hydrochloric Acid...% CAS # 7647-01-0	5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

NIOSH

Hydrochloric Acid...% CAS # 7647-01-0	50 ppm IDLH

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Section 8 Exposure Controls and Personal Protection (Continued)

	Japan	None established
8.2	**Exposure controls**	
	Engineering Controls	No special engineering controls are required. Use with good general ventilation.
	Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
	Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
	Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.005 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	1	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Hydrochloric Acid...% no geometric mean air odor threshold		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity — No further relevant information available.

10.2 Chemical Stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid — To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Hydrochloric Acid...% CAS # 7647-01-0	Inhalation LC50 Rat 3124 ppm 1 h; Oral LD50 Rat 700 mg/kg; Dermal LD50 Rabbit >5010 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Causes severe skin burns.
Serious eye damage/eye irritation	Causes serious eye damage.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — No further relevant information available.

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Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	**UN/ID Number**	1789	1789	1789	1789	PIN - 1789
14.2	**Shipping Name**	Hydrochloric acid solution				
14.3	**Hazard Class**	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
14.4	**Packing Group**	II	II	II	II	II
	Special Provisions	Not applicable	None	A3, A6	Not applicable	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable

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Section 14 Transport Information (Continued)

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	157	Not applicable	157

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Hydrochloric Acid...% is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Hydrochloric Acid...% is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Hydrochloric Acid...% is listed.

New Jersey Dept. of Health RTK List

Hydrochloric Acid...% is listed.

Pennsylvania RTK Hydrochloric Acid...% is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1789

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Hydrochloric Acid...%

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 1** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
R34 Causes burns.
R37 Irritating to respiratory system.
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Skin Corr. 1B - Skin Corrosion Category 1B
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H335 - May cause respiratory irritation.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration

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Section 16 Other Information (Continued)

PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 598190-75 Rev. AG
Revised (year/month/day) 2015/05/28

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Trace-Klean™ Ready to Use Cleaning Solution

Part Number 598190

Series Name DU700

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For laboratory use only. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Potassium Hydroxide

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Potassium Hydroxide CAS # 1310-58-3 EINECS # 215-181-3 Index # 019-002-00-8	< 1	C;R22-35	Acute Tox. Oral 4 Eye Dam. 1 Skin Corr. 1A H302; H314; H318	Acute Tox. Oral 4 Aquatic Acute 3 Eye Dam. 1 Skin Corr. 1A H302; H314; H318; H402	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open and obtain medical attention immediately.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

If eye irritation persists: Get medical advice/attention.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions — Observe general safety guidelines for protection; avoid eye and skin contact.

Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions — Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 30°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Potassium Hydroxide
CAS # 1310-58-3 — 2 mg/m3 Ceiling

DFG MAK None established

Ireland

Potassium Hydroxide
CAS # 1310-58-3 — 2 mg/m3 STEL

IOELVs None established

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	>= 12	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Potassium Hydroxide CAS # 1310-58-3	Oral LD50 Rat 214 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Causes severe skin burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability

Not determined for the product.

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Section 12 Ecological Information (Continued)

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1814	1814	1814	1814	PIN - 1814
14.2	Shipping Name	Potassium Hydroxide Solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	Packing Group	III	III	III	III	III
	Special Provisions	Not applicable	Not applicable	Not applicable	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

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Section 14 Transport Information (Continued)

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Formaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Diethanolamine is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sulfuric Acid is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Formaldehyde is listed.

Ethylene Oxide is listed.

Diethanolamine is listed.

1,4-Dioxane is listed.

Potassium Hydroxide is listed.

Sulfuric Acid is listed.

Richonic Acid B is listed.

California Proposition 65

Formaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Diethanolamine has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause cancer.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Sulfur Dioxide has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Sulfuric Acid has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Formaldehyde is listed.
Ethylene Oxide is listed.
Triethanolamine is listed.
Diethanolamine is listed.
1,4-Dioxane is listed.
Potassium Hydroxide is listed.
Sulfur Dioxide is listed.
Sulfuric Acid is listed.
Richonic Acid B is listed.

New Jersey Dept. of Health RTK List

Formaldehyde is listed.
Ethylene Oxide is listed.
Triethanolamine is listed.
Diethanolamine is listed.
1,4-Dioxane is listed.
Potassium Hydroxide is listed.
Sulfur Dioxide is listed.
Sulfuric Acid is listed.
Richonic Acid B is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Formaldehyde is listed.
Ethylene Oxide is listed.
Triethanolamine is listed.
Diethanolamine is listed.
1,4-Dioxane is listed.
Potassium Hydroxide is listed.
Sulfur Dioxide is listed.
Sulfuric Acid is listed.
Richonic Acid B is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1814

Ingredients on Ingredient Disclosure List

Formaldehyde
Ethylene Oxide
Triethanolamine
Diethanolamine
1,4-Dioxane
Potassium Hydroxide
Sulfur Dioxide
Sulfuric Acid
Dodecylbenzenesulphonic acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Revise product use statement.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
R22 Harmful if swallowed.
R35 Causes severe burns.
Aquatic Acute 3 - Aquatic Hazard Acute, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Skin Corr. 1A - Skin Corrosion Category 1A
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.
H402 - Harmful to aquatic life.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6152-75: Version 05
Revision Date (year/month/day) 2020/04/08
Last Revision Date (year/month/day) 2019/03/12

Product Information

Product Name	TRANSFERRIN
Part Number	OSR6152

Components

Description	Transferrin R1 Transferrin R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Document ID: OSR6152-75 Version 05
Revision Date (year/month/day) 2020/04/08
Last Revision Date (year/month/day) 2019/03/12

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Transferrin R1

Part Number Component of P/N OSR6152

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

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TRANSFERRIN
Transferrin R1

Section 2 Hazards (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Tris(hydroxymethyl)– aminomethane

Pictogram

None

Signal Word

WARNING

Hazard Statements

H316 Causes mild skin irritation.

Precautionary Statements

P332+P313 If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Tris(hydroxymethyl)– aminomethane CAS # 77-86-1 EINECS # 201-064-4 Index # Not available	1 - 5	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

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TRANSFERRIN
Transferrin R1

SAFETY DATA SHEET
Document ID: OSR6152-75 Version 05
Revision Date (year/month/day) 2020/04/08
Last Revision Date (year/month/day) 2019/03/12

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

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TRANSFERRIN
Transferrin R1

Section 6 Accidental Release Measures (Continued)

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan	None established
Sweden (AFS 2015:7 and amendments)	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	7.2	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	250°C (482°F)	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Last Revision Date (year/month/day) 2019/03/12

Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	Metals and metallic compounds
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Tris(hydroxymethyl)–aminomethane CAS # 77-86-1	Oral LD50 Rat 5900 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

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Last Revision Date (year/month/day) 2019/03/12

Section 11 Toxicological Information (Continued)

Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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		To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
		Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

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Section 15 Regulatory Information (Continued)

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated Section 8.
Updated Section 11.

Document version and issue/revision date

Revision Date (year/month/day) 2020/04/08

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Section 16 Other Information (Continued)

Last Revision Date (year/month/day) 2019/03/12
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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Irrit. 2 - Skin Irritation Category 2
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Transferrin R2

Part Number Component of P/N OSR6152

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless to amber; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product.

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.03
Color	Colorless to amber	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Mild odor	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Global SDS – English

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Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated Section 2.
Updated Section 8.
Updated Section 9.
Updated Section 11.

Document version and issue/revision date

Revision Date (year/month/day) 2020/04/08
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Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Information Sheet

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code:	**108C.USE**
Product name	**Transystem AMIES w/o ch plastic applicator rayon tipped**

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use: **CULTURE SWAB TRANSPORT SYSTEM**

Identified Uses	Industrial	Professional	Consumer
Transport and conservation of clinical specimens for diagnostic analysis	-	✓	-

1.3. Details of the supplier of the safety data sheet

Name	**Copan Italia SPA**
Full address	**Via Perotti 10**
District and Country	**25125 Brescia (BS)**
	Italy
	Tel. 0302687200
	Fax 0302687250
e-mail address of the competent person responsible for the Safety Data Sheet	**msds@copanitalia.com**

Legal Manufacturer: Copan Italia SpA - Italy

1.4. Emergency telephone number

For urgent inquiries refer to: **+39 0302687200**

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication: --

2.2. Label elements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

SECTION 3. Composition/information on ingredients. ... / >>

3.2. Mixtures.

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions set forth in Directives 67/548/EEC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

SECTION 4. First aid measures.

4.1. Description of first aid measures.
Not specifically necessary. Observance of good industrial hygiene is recommended.

4.2. Most important symptoms and effects, both acute and delayed.
No episodes of damage to health ascribable to the product have been reported.

4.3. Indication of any immediate medical attention and special treatment needed.
Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.
SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture.
HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.

5.3. Advice for firefighters.
GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.
Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.
The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.
Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.
Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.
Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities.
Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).
Product Pack Insert may be available, ask to legal manufacturer.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Information not available.

8.2. Exposure controls.

Comply with the safety measures usually applied when handling chemical substances.
HAND PROTECTION
None required.
SKIN PROTECTION
None required.
EYE PROTECTION
None required.
RESPIRATORY PROTECTION
None required, unless indicated otherwise in the chemical risk assessment.
ENVIRONMENTAL EXPOSURE CONTROLS.
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	white
Odour	Not available.
Odour threshold.	Not available.
pH.	7,10 - 7,50 a 20°C - 25°C
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	Not available.
Solubility	Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Molecular weight.	20,087
Solid content.	2,20 %
VOC (Directive 1999/13/EC) :	0
VOC (volatile carbon) :	0

SECTION 10. Stability and reactivity.

10.1. Reactivity.
There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.
The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.
No hazardous reactions are foreseeable in normal conditions of use and storage.

SECTION 10. Stability and reactivity. ... / >>

10.4. Conditions to avoid.
None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.
Information not available.

10.6. Hazardous decomposition products.
Information not available.

SECTION 11. Toxicological information.

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good practices.

11.1. Information on toxicological effects.

Information not available.

SECTION 12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

12.1. Toxicity.
Information not available.

12.2. Persistence and degradability.
Information not available.

12.3. Bioaccumulative potential.
Information not available.

12.4. Mobility in soil.
Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.
Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

SECTION 14. Transport information. ... / >>

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information.

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.
None.

Substances in Candidate List (Art. 59 REACH).
None.
Substances subject to authorisarion (Annex XIV REACH).
None.
Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None.

Substances subject to the Rotterdam Convention:
None.

Substances subject to the Stockholm Convention:
None.

Healthcare controls.
Information not available.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level

SECTION 16. Other information. ... / >>

- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EU) 1907/2006 (REACH) of the European Parliament
4. Regulation (EU) 1272/2008 (CLP) of the European Parliament
5. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 453/2010 of the European Parliament
7. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
9. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- Niosh - Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- ECHA website

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:
The following sections were modified:
02 / 09 / 14.

MATERIAL SAFETY DATA SHEET

TF21010 SERIES
03 00

DATE OF PREPARATION
Apr 14, 2017

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
TF21010 SERIES

PRODUCT NAME
TRI-FLOW® Industrial Lubricant, TF21010,TF21060,TF29200

MANUFACTURER'S NAME
TRI-FLOW INDUSTRIAL GROUP
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.triflowlubricants.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
**for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)*	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
30	**64742-47-8**	**Aliphatic Solvent**		
		ACGIH TLV	Not Available	0.00787 mm
		OSHA PEL	Not Available	
52	**64742-52-5**	**Heavy Naphthenic Petroleum Oil**		
		ACGIH TLV	5 mg/m3 as Mist	
		OSHA PEL	5 mg/m3 as Mist	
4	**64742-65-0**	**Heavy Paraffinic Oil**		
		ACGIH TLV	5 mg/m3 as Mist	
		OSHA PEL	5 mg/m3 as Mist	
3	**628-63-7**	**Amyl Acetate**		
		ACGIH TLV	100 PPM	4 mm
		OSHA PEL	100 PPM	

SECTION 3 — HAZARDS IDENTIFICATION

HMIS Codes

Health	2
Flammability	2
Reactivity	0

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.

EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

May cause nervous system depression. Extreme overexposure may result in unconsciousness and possibly death.

SIGNS AND SYMPTOMS OF OVEREXPOSURE
Headache, dizziness, nausea, and loss of coordination are indications of excessive exposure to vapors or spray mists. Redness and itching or burning sensation may indicate eye or excessive skin exposure.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.

CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
181 °F PMCC	0.7	7.5	Combustible, Flash above 99 and below 200 °F

EXTINGUISHING MEDIA

Carbon Dioxide, Dry Chemical, Foam

UNUSUAL FIRE AND EXPLOSION HAZARDS

Closed containers may explode when exposed to extreme heat.
Application to hot surfaces requires special precautions.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.

SPECIAL FIRE FIGHTING PROCEDURES

Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED

Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY

DOL Storage Class IIIA

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE

Contents are COMBUSTIBLE. Keep away from heat and open flame.
Consult NFPA Code. Use approved Bonding and Grounding procedures.
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE

Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.

VENTILATION

Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.

RESPIRATORY PROTECTION

If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.

PROTECTIVE GLOVES

Wear gloves which are recommended by glove supplier for protection against materials in Section 2.

EYE PROTECTION

Wear safety spectacles with unperforated sideshields.

OTHER PRECAUTIONS

Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	7.31 lb/gal	876 g/l
SPECIFIC GRAVITY	0.88	
BOILING POINT	288 - 460 °F	142 - 237 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	36%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

2.40 lb/gal	287 g/l	Less Water and Federally Exempt Solvents
2.40 lb/gal	287 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable

CONDITIONS TO AVOID

None known.

INCOMPATIBILITY

None known.

HAZARDOUS DECOMPOSITION PRODUCTS

By fire: Carbon Dioxide, Carbon Monoxide

HAZARDOUS POLYMERIZATION

Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS

No ingredient in this product is an IARC, NTP or OSHA listed carcinogen.

Reports have associated repeated and prolonged overexposure to solvents with permanent brain and nervous system damage.

TOXICOLOGY DATA

CAS No.	Ingredient Name			
64742-47-8	**Aliphatic Solvent**			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
64742-52-5	**Heavy Naphthenic Petroleum Oil**			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
64742-65-0	**Heavy Paraffinic Oil**			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
628-63-7	**Amyl Acetate**			
		LC50 RAT	4HR	Not Available
		LD50 RAT		6500 mg/kg

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION

No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD

Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.

Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.
Bulk Containers may be Shipped as:
NA1993, COMBUSTIBLE LIQUID, N.O.S. (AMYL ACETATES), PG III, (ERG#128)
Canada (TDG)
Not Regulated for Transportation.
IMO
Not Regulated for Transportation.
IMO
Not Regulated for Transportation.
IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element
	Barium Compound	3	0.07

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

Kit SDS Cover Sheet

Document ID: OSR61118-75: Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/02/10

Product Information

Product Name	Triglyceride
Part Number	OSR61118, OSR66118, OSR60118

Components

Description	Triglyceride R1
	Triglyceride R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Document ID: OSR61118-75 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/02/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Triglyceride R1

Part Number Component of P/N OSR60118, OSR61118, OSR66118

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Lismeehan O'Callaghan's Mills Co. Clare Ireland Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Light yellow; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

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BECKMAN COULTER
Triglyceride
Triglyceride R1

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # 618-344-0 Index # Not available	0.1 - 1	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	8, AUTH, SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
AUTH - Subject to Authorisation as per EU - REACH (1907/2006) Annex XIV
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

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BECKMAN COULTER
Triglyceride
Triglyceride R1

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Light yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide
CAS # 26628-22-8

96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 10043-35-3 Boric Acid

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 3.

Updated Section 8, 11, 15, 16.

Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28

Last Revision Date (year/month/day) 2017/02/10

Document ID: OSR61118-75

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Section 16 Other Information (Continued)

Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
H300 - Fatal if swallowed.
H302 - Harmful if swallowed.
H318 - Causes serious eye damage.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: OSR61118-75 Version 07
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/02/10

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Triglyceride R2

Part Number Component of P/N OSR60118, OSR61118, OSR66118

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Dark yellow; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

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Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Dark yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	7.5	**Partition n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0°C	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Global SDS – English

Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS # 26628-22-8 — Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.
12.5 Results of PBT and vPvB assessment	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6 Other Adverse Effects	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Triglyceride
Triglyceride R2

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration
CAS # 13746-66-2	Potassium Ferricyanide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

CAS # 13746-66-2 Potassium Ferricyanide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

CAS # 13746-66-2 Potassium Ferricyanide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 8, 11, 15, 16.

Updated Section 12.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2017/02/10
Document ID: OSR61118-75
Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Global SDS – English

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Doc. ID: 445850-75: Rev. AG
Revised (year/month/day) 2015/05/08

Product Information

Product Name	Triglycerides Reagent
Part Number	445850
Series Name	SYNCHRON Systems

Components

Description

Triglycerides Reagent (Compartment A)
Triglycerides Reagent (Compartment B)
Triglycerides Reagent (Compartment C)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 445850-75 Rev. AG
Revised (year/month/day) 2015/05/08

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Triglycerides Reagent (Compartment A)

Part Number Component of P/N 445850

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Clear to pink; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.
Use good laboratory procedures; avoid eye and skin contact.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain efficacy, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.007 @20°C
Color	Clear to pink	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.35 - 6.45	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	Reproductive effects have been reported in animal studies.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Formaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Formaldehyde is listed.
Ethylene Oxide is listed.
Sodium Azide is listed.

California Proposition 65

Formaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Massachusetts MSL

Formaldehyde is listed.
Ethylene Oxide is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Formaldehyde is listed.
Ethylene Oxide is listed.
Sodium Azide is listed.

Pennsylvania RTK

Formaldehyde is listed.
Ethylene Oxide is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Formaldehyde
Ethylene Oxide
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

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Section 15 Regulatory Information (Continued)

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

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Section 16 Other Information (Continued)

TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: 445850-75 Rev. AG
Revised (year/month/day) 2015/05/08

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Triglycerides Reagent (Compartment B)

Part Number Component of P/N 445850

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellow; Clear; Liquid; Mild odor

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.

See Section 11 Toxicological Information for more detailed health information.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.
Observe general safety guidelines for protection; avoid eye and skin contact.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.
Use good laboratory procedures; avoid eye and skin contact.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain efficacy, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.01307 @20°C
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	6.55 - 6.65	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Causes mild skin irritation.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	Reproductive effects have been reported in animal studies.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T+ - Very toxic
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 445850-75 Rev. AG
Revised (year/month/day) 2015/05/08

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Triglycerides Reagent (Compartment C)

Part Number Component of P/N 445850

Series Name SYNCHRON Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless to slightly brown; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

	Flammable Properties	Nonflammable aqueous solution.
5.1	**Extinguishing Media**	In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.
5.2	**Special hazards arising from the substance or mixture**	
	Special Fire and Explosion Hazards	No special hazards determined.
	Hazardous Combustion Products	No combustion products posing significant hazards are expected from this product (an aqueous solution).
5.3	**Advice for fire fighters**	
	Protective Equipment	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
5.4	**Additional information**	No further relevant information available.

Section 6 Accidental Release Measures

6.1	**Personal precautions, protective equipment and emergency procedures**	
	Personal Precautions	Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.
6.2	**Environmental Precautions**	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
6.3	**Methods and material for containment and cleaning up**	
	Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4	**Reference to other sections**	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1	**Precautions for safe handling**	Use good laboratory procedures; avoid eye and skin contact.
7.2	**Conditions for safe storage, including any incompatibilities**	
		Store at 2 to 8°C , as directed on the product label. To maintain efficacy, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
7.3	**Specific end uses**	No further relevant information available.

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Global SDS – English

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.0 @20°C
Color	Colorless to slightly brown	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not determined
pH	6.35 - 6.45	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

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concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

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Section 15 Regulatory Information (Continued)

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

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Section 16 Other Information (Continued)

PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Doc. ID: IM1724-75: Rev. AA
Issued (year/month/day) 2015/05/04

Product Information

Product Name TSH ILMA

Part Number IM1724

Additional Product Information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description

HRP-labeled anti-TSH monoclonal antibody conjugate
TSH ILMA Calibrators
TSH IRMA controls
Conjugate diluent

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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SAFETY DATA SHEET

Doc. ID: IM1724-75 Rev. AA
Issued (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name HRP-labeled anti-TSH monoclonal antibody conjugate

Part Number Component of P/N IM1724

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Global SDS – English

Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	No further relevant information available.
10.4	**Conditions to Avoid**	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard — No data available.

Other Information — This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability — Not determined for the product.

12.3 Bioaccumulation — Not determined for the product.

12.4 Mobility in soil — Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects — No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated to GHS.	

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Global SDS – English

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1724-75 Rev. AA
Issued (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name TSH ILMA Calibrators

Part Number Component of P/N IM1724

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellowish; Clear; Lyophilized Powder - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.
Combustion products may contain minute amounts of mercury.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Carefully sweep up spilled material and place in a container suitable for disposal. Avoid generating dust.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

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Section 11 Toxicological Information (Continued)

Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information. This product contains a low level (<0.05%) of Thimerosal. Specific federal, state, and local regulations for disposal of mercury compounds may apply.

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Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2 Additional information	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
California Proposition 65	Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause reproductive harm. Thimerosal has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause reproductive harm.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.
Pennsylvania RTK	No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Thimerosal

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1724-75 Rev. AA
Issued (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name TSH IRMA controls

Part Number Component of P/N IM1724

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellowish; Clear; Lyophilized Powder - Liquid after reconstitution.; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.
Combustion products may contain minute amounts of mercury.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Carefully sweep up spilled material and place in a container suitable for disposal. Avoid generating dust.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder - Liquid after reconstitution.	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

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Section 11 Toxicological Information (Continued)

Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information. This product contains a low level (<0.05%) of Thimerosal. Specific federal, state, and local regulations for disposal of mercury compounds may apply.

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Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2 Additional information	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
California Proposition 65	Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause reproductive harm. Thimerosal has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause reproductive harm.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.
Pennsylvania RTK	No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Thimerosal

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: IM1724-75 Rev. AA
Issued (year/month/day) 2015/05/04

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Conjugate diluent

Part Number Component of P/N IM1724

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Blue; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Citric Acid CAS # 77-92-9 EINECS # 201-069-1 Index # Not available	3 - 4	Xi;R36	Eye Irrit. 2 H319	Eye Irrit. 2 H319	3, 8

3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.
Combustion products may contain minute amounts of mercury.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
Carefully sweep up spilled material and place in a container suitable for disposal. Avoid generating dust.
Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Blue	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Odorless	**Organic**	Not determined
	pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
	Boiling Point	Not determined	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	No data available.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	
	No data available.
Specific target organ toxicity – repeated exposure	
	No data available.
Aspiration hazard	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	
	Citric Acid CAS # 77-92-9	96 h LC50 Lepomis macrochirus: 1516 mg/L [static]
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

This product contains a low level (<0.05%) of Thimerosal. Specific federal, state, and local regulations for disposal of mercury compounds may apply.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

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Section 15 Regulatory Information (Continued)

California Proposition 65

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Neomycin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Thimerosal has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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Section 15 Regulatory Information (Continued)

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Thimerosal
Acetaldehyde
Ethylene Oxide
Citric Acid
1,4-Dioxane

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

Xi - Irritant
R36 Irritating to eyes.
Eye Irrit. 2 - Eye Irritation Category 2
H319 - Causes serious eye irritation.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods

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Section 16 Other Information (Continued)

IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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Kit SDS Cover Sheet

Document ID: OSR6198: Version 07
Revision Date (year/month/day) 2020/05/14
Last Revision Date (year/month/day) 2019/03/12

Product Information

Product Name	Uric acid
Part Number	OSR6198, OSR6298, OSR6698, OSR6098

Components

Description	URIC ACID R1 URIC ACID R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6198 Version 07
Revision Date (year/month/day) 2020/05/14
Last Revision Date (year/month/day) 2019/03/12

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name URIC ACID R1

Part Number Component of P/N OSR6098, OSR6198, OSR6298, OSR6698

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Aquatic Hazard Long term, Category 3

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BECKMAN COULTER
Uric acid
URIC ACID R1

SAFETY DATA SHEET
Document ID: OSR6198 Version 07
Revision Date (year/month/day) 2020/05/14
Last Revision Date (year/month/day) 2019/03/12

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3
Aquatic Hazard Long term, Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.7.5% of product contains ingredients of unknown hazards to aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Section 3 Composition and Information on Ingredients (Continued)

Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # 618-344-0 Index # Not available	0.1 - < 1	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	8, SVHC
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

Sweden (AFS 2015:7 and amendments)

None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Not miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	7.0	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

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Section 11 Toxicological Information (Continued)

Acute Toxicity	Not	based on available data.
Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.	
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.	

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.

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BECKMAN COULTER
Uric acid
URIC ACID R1

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

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Section 15 Regulatory Information (Continued)

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0 Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 2, water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Update of product hazard and label elements in Sec. 2.
Updated the concentration range of hazardous ingredient in Sec. 3.
Updated hazard of pure ingredient in Sec. 3.
Updated Section 4, 11, 12, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/05/14
Last Revision Date (year/month/day) 2019/03/12
Document ID: OSR6198
Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

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Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name URIC ACID R2

Part Number Component of P/N OSR6098, OSR6198, OSR6298, OSR6698

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Yellow-brown; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

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Uric acid
URIC ACID R2

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Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

2.3 Other hazards

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		**Hazard**	**of Pure Ingredients**	
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # 618-344-0 Index # Not available	0.1 - < 1	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 2, H411 Eye Dam. 1, H318	8, SVHC
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

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Section 4 First Aid Measures (Continued)

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

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Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	Not determined
Color	Yellow-brown	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Characteristic odor	**Organic**	Not determined
pH	7.8	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Polyoxyethylated Octyl Phenol CAS # 9002-93-1	Oral LD50 Rat 1800 mg/kg
Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration
CAS # 14459-95-1	Potassium Ferrocyanide, Trihydrate	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 1405-41-0	Gentamicin Sulfate

Chemical which is known to the State of California to cause male reproductive toxicity

CAS # 14459-95-1	Potassium Ferrocyanide, Trihydrate

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

CAS # 14459-95-1 Potassium Ferrocyanide, Trihydrate

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

CAS # 14459-95-1 Potassium Ferrocyanide, Trihydrate

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated the concentration range of hazardous ingredient in Sec. 3.
Updated Section 8, 11, 15.

Document version and issue/revision date

Revision Date (year/month/day) 2020/05/14
Last Revision Date (year/month/day) 2019/03/12
Document ID: OSR6198
Version: 07

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2

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Section 16 Other Information (Continued)

H300 - Fatal if swallowed.
H302 - Harmful if swallowed.
H318 - Causes serious eye damage.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Document ID: OSR6170-75: Version 06
Revision Date (year/month/day) 2020/06/18
Last Revision Date (year/month/day) 2019/04/11

Product Information

Product Name	Urinary / CSF Protein
Part Number	OSR6170, OSR6270

Components

Description	Urinary/CSF Protein R1 Urinary/CSF Protein Calibrator

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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SAFETY DATA SHEET

Document ID: OSR6170-75 Version 06
Revision Date (year/month/day) 2020/06/18
Last Revision Date (year/month/day) 2019/04/11

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urinary/CSF Protein R1

Part Number Component of P/N OSR6170, OSR6270

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Lismeehan O'Callaghan's Mills Co. Clare Ireland Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Dark red; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Target Organ Toxicity Single Exposure Category 1

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Urinary / CSF Protein
Urinary/CSF Protein R1

Section 2 Hazards (Continued)

2.2 Label Elements

According to US-OSHA / UN GHS

Hazardous Ingredients

Methanol

Pictogram

Signal Word

DANGER

Hazard Statements

H370 Causes damage to organs.

Precautionary Statements

P260 Do not breathe vapours.
P264 Wash hands thoroughly after handling.
P270 Do no eat, drink or smoke when using this product.
P308+P311 If exposed or concerned: Call a doctor/physician.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Methanol CAS # 67-56-1 EINECS # 200-659-6 Index # 603-001-00-X	1 - 2	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Flam. Liq. 2, H225 STOT SE 1, H370	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Flam. Liq. 2, H225 STOT SE 1, H370	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

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Urinary / CSF Protein
Urinary/CSF Protein R1

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Last Revision Date (year/month/day) 2019/04/11

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause damage to organs.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

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Section 6 Accidental Release Measures (Continued)

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Methanol
CAS # 67-56-1 200 ppm TWA; 260 mg/m3 TWA

ACGIH

Methanol
CAS # 67-56-1 250 ppm STEL; 200 ppm TWA; Skin - potential contribution to overall exposure by the cutaneous route

DFG MAK

Methanol
CAS # 67-56-1 skin notation; 200 ppm Peak; 260 mg/m3 Peak; 100 ppm TWA MAK; 130 mg/m3 TWA MAK

Ireland

Methanol
CAS # 67-56-1 200 ppm TWA; 260 mg/m3 TWA; 600 ppm STEL (calculated); 780 mg/m3 STEL (calculated); Potential for cutaneous absorption

IOELVs

Methanol
CAS # 67-56-1 Possibility of uptake through the skin; 200 ppm TWA; 260 mg/m3 TWA

NIOSH

Methanol
CAS # 67-56-1 6000 ppm IDLH; 250 ppm STEL; 325 mg/m3 STEL; 200 ppm TWA; 260 mg/m3 TWA

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan

Methanol CAS # 67-56-1	200 ppm OEL; 260 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

Methanol CAS # 67-56-1	200 ppm TLV; 250 mg/m3 TLV; 250 ppm Indicative STEL; 350 mg/m3 Indicative STEL; Skin notation

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.00 @20°C
Color	Dark red	**Solubility**	
Transparency	Clear	**Water**	Not miscible
Odor	Odorless	**Organic**	Not determined
pH	2.5 @20°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable

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Urinary / CSF Protein
Urinary/CSF Protein R1

Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Methanol 3.05 ppm odor threshold value (detectable)
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	
		No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	
		No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Methanol CAS # 67-56-1	Dermal LD50 Rabbit 15840 mg/kg; Inhalation LC50 Rat 22500 ppm 8 h; Oral LD50 Rat 6200 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.

target organ toxicity – single exposure

May cause damage to organs.

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Section 11 Toxicological Information (Continued)

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Methanol
CAS # 67-56-1

96 h LC50 Pimephales promelas: 28200 mg/L -through]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 19500 - 20700 mg/L -through]; 96 h LC50 Oncorhynchus mykiss: 18 - 20 mL/L [static]; 96 h LC50 Lepomis macrochirus: 13500 - 17600 mg/L -through]

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 67-56-1 Methanol 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 67-56-1 Methanol

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

CAS # 67-56-1 Methanol

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 67-56-1 Methanol

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 67-56-1 Methanol

Pennsylvania Right To Know (RTK) List

CAS # 67-56-1 Methanol

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated Section 8.
Updated Section 15 Regulatory Information.

Document version and issue/revision date

Revision Date (year/month/day) 2020/06/18
Last Revision Date (year/month/day) 2019/04/11
Document ID: OSR6170-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Flam. Liq. 2 - Flammable Liquids, Category 2
STOT SE 1 - Target Organ Toxicity Single Exposure Category 1
H225 - Highly liquid and vapour.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.

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Section 16 Other Information (Continued)

	H331 - Toxic if inhaled.
	H370 - Causes damage to organs.
	H370 - Causes damage to organs (Respiratory system)
	H370 - Causes damage to organs (Liver and Kidney)
	H370 - Causes damage to organs (Kidney)
	H370 - Causes damage to organs (Liver)
Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists
	ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
	CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
	CLP - Labeling and Packaging
	DFGMAK - Republic Germany's maximum exposure limit
	GHS - Globally Harmonized System
	HCS - Hazard Communication Standard
	IARC - International Agency for Research on Cancer
	IATA DGR - International Air Transport Association Dangerous Goods Regulation
	ICAO - International Civil Aviation Organization
	IMDG - International Maritime Dangerous Goods
	IOELVs - European Unions' Indicative Occupational Exposure Limit Values
	NIOSH - National Institute for Occupational Safety and Health
	NTP - National Toxicology Program
	OSHA - Occupational Safety and Health Administration
	PBT - Persistent bioaccumulative and toxic substances
	SARA - Superfund Amendments and Reauthorization Act
	TDG - Canadian Transportation Of Dangerous Goods Regulations.
	UN GHS - United Nations Globally Harmonized System
	US DOT - United States Department of Transportation
	WHMIS - Workplace Hazardous Material Information System
	vPvB - Very persistent and very bioaccumulative substances
	LD50 - Lethal Dose, 50%
	LC50 - Lethal Concentration, 50%

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SAFETY DATA SHEET

Document ID: OSR6170-75 Version 06
Revision Date (year/month/day) 2020/06/18
Last Revision Date (year/month/day) 2019/04/11

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urinary/CSF Protein Calibrator

Part Number Component of P/N OSR6170, OSR6270

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Characteristic odor

according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Aquatic Hazard Long term, Category 3

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Urinary / CSF Protein
Urinary/CSF Protein Calibrator

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

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Urinary / CSF Protein
Urinary/CSF Protein Calibrator

SAFETY DATA SHEET
Document ID: OSR6170-75 Version 06
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Last Revision Date (year/month/day) 2019/04/11

Section 3 Composition and Information on Ingredients (Continued)

Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May cause sensitization by skin contact.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture
Special Fire and Explosion Hazards

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Section 5 Fire Fighting Measures (Continued)

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Not miscible

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Section 9 Physical and Chemical Properties (Continued)

	Odor	Characteristic odor	**Organic**	Not determined
	pH	Not determined	**Partition n-octanol/water**	Not determined
	Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
	Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
	Flash Point	Not applicable	**Percent Volatiles**	Not applicable
	Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
	Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
	Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product is as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Update of product hazard and label elements in Sec. 2.
Updated hazard of pure ingredient in Sec. 3.
Updated Section 8, 12, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/06/18
Last Revision Date (year/month/day) 2019/04/11
Document ID: OSR6170-75
Version: 06

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A

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Section 16 Other Information (Continued)

H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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SAFETY DATA SHEET

Document ID: DR0091-75 Version AG
Revision Date (year/month/day) 2018/09/24
Last Revision Date (year/month/day) 2015/10/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urine Creatinine Calibrator

Part Number DR0091

Series Name AU US

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description Mixture

Colorless to light yellow; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Hazardous Ingredients

Hydrochloric Acid

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

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Section 2 Hazards (Continued)

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Hydrochloric Acid CAS # 7647-01-0 EINECS # 231-595-7 Index # 017-002-01-X	1 - 3	Acute Tox. Oral 4, H302 STOT SE 3, H335 Skin Corr. 1B, H314	Acute Tox. Oral 4, H302 STOT SE 3, H335 Skin Corr. 1B, H314	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

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Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Avoid inhaling, ingesting, and contact with eyes and skin.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Hydrochloric Acid
CAS # 7647-01-0: 5 ppm Ceiling; 7 mg/m3 Ceiling

ACGIH

Hydrochloric Acid
CAS # 7647-01-0: 2 ppm Ceiling

DFG MAK

Hydrochloric Acid
CAS # 7647-01-0: 4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

Ireland

Hydrochloric Acid
CAS # 7647-01-0: 5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

IOELVs

Hydrochloric Acid
CAS # 7647-01-0: 10 ppm STEL; 15 mg/m3 STEL; 5 ppm TWA; 8 mg/m3 TWA

NIOSH

Hydrochloric Acid
CAS # 7647-01-0: 50 ppm IDLH

Japan: None established

Sweden (AFS 2015:7 and amendments)

Hydrochloric Acid
CAS # 7647-01-0: 2 ppm TLV; 3 mg/m3 TLV; 4 ppm Binding STEL; 6 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls: No special engineering controls are required. Use with good general ventilation.

Eye Protection: Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.00 - 1.03 @20°C
Color	Colorless to light yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	< 1.5	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Hydrochloric Acid 0.06 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

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Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Hydrochloric Acid CAS # 7647-01-0	Dermal LD50 Rabbit >5010 mg/kg; Inhalation LC50 Rat 1.68 mg/L 1 h; Oral LD50 Rat 238 - 277 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Causes severe skin burns.
Serious eye damage/eye irritation	Causes serious eye damage.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

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Section 12 Ecological Information (Continued)

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	**UN/ID Number**	1789	1789	1789	1789	PIN - 1789
14.2	**Shipping Name**	Hydrochloric acid solution				
14.3	**Hazard Class**	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
14.4	**Packing Group**	III	III	III	III	III
	Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	157	Not applicable	157

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Section 14 Transport Information (Continued)

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

No special precautions for users are required.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 7647-01-0 Hydrochloric Acid 1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 7647-01-0 Hydrochloric Acid

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

Pennsylvania Right To Know (RTK) List

CAS # 7647-01-0 Hydrochloric Acid

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated Section 4.
Updated Section 8.
Updated Section 11.
Updated Section 15.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2018/09/24
Last Revision Date (year/month/day) 2015/10/20
Document ID: DR0091-75
Version: AG

Description of hazard Class and hazard statements from Section 3

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Skin Corr. 1B - Skin Corrosion Category 1B
STOT SE 3 - Target Organ Toxicity Single Exposure Category 3
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H335 - May cause respiratory irritation.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation

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BECKMAN COULTER
Urine Creatinine Calibrator

SAFETY DATA SHEET

Document ID: DR0091-75 Version AG
Revision Date (year/month/day) 2018/09/24
Last Revision Date (year/month/day) 2015/10/20

Section 16 Other Information (Continued)

ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Kit SDS Cover Sheet

Document ID: B38858-75: Version 05
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2018/08/22

Product Information

Product Name	Urine/CSF Albumin
Part Number	B46435, B38858

Components

Description	Urine/CSF Albumin R1 Urine/CSF Albumin R2

Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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Global SDS – English

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SAFETY DATA SHEET

Document ID: B38858-75 Version 05
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2018/08/22

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urine/CSF Albumin R1

Part Number Component of P/N B38858, B46435

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

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Urine/CSF Albumin
Urine/CSF Albumin R1

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

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Urine/CSF Albumin
Urine/CSF Albumin R1

Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

No special precautions are necessary; use good laboratory procedures.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.9 - 7.1 @24°C	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Urine/CSF Albumin
Urine/CSF Albumin R1

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.	
Acute Toxicity	Not	based on available data.
Skin Corrosion/Irritation	Not	based on available data.
Serious eye damage/eye irritation	Not	based on available data.
Respiratory/skin sensitization	Not	based on available data.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.	
Germ cell mutagenicity	Not	based on available data.
Reproductive Toxicity	Not	based on available data.
target organ toxicity – single exposure		
	Not	based on available data.
target organ toxicity – repeated exposure		
	Not	based on available data.
Aspiration hazard	Not	based on available data.
Other Information	No further relevant information available.	

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]

Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Urine/CSF Albumin
Urine/CSF Albumin R1

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 107-21-1	Ethylene Glycol	1.0% de minimis concentration
CAS # 75-21-8	Ethylene Oxide	0.1% de minimis concentration
CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 107-21-1	Ethylene Glycol
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause development toxicity

CAS # 107-21-1	Ethylene Glycol
CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause male reproductive toxicity

CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause female reproductive toxicity

CAS # 75-21-8	Ethylene Oxide

Massachusetts Right To Know (RTK) List

CAS # 107-21-1	Ethylene Glycol
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 107-21-1	Ethylene Glycol
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 107-21-1	Ethylene Glycol
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated Section 8, 11, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2018/08/22
Document ID: B38858-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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SAFETY DATA SHEET

Document ID: B38858-75 Version 05
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2018/08/22

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urine/CSF Albumin R2

Part Number Component of P/N B38858, B46435

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Transparent; Liquid; Odorless

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

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BECKMAN COULTER
Urine/CSF Albumin
Urine/CSF Albumin R2

Section 2 Hazards (Continued)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

2.3 Other hazards

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

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Section 4 First Aid Measures (Continued)

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections Refer sections 8 and 13.

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Urine/CSF Albumin
Urine/CSF Albumin R2

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Transparent	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.0	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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Section 10 Stability and Reactivity (Continued)

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Not based on available data.

Serious eye damage/eye irritation Not based on available data.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8	Sodium Azide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8	Sodium Azide

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated E-mail address in Sec. 1.3.
Updated Section 8, 11, 15, 16.

Document version and issue/revision date

Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2018/08/22
Document ID: B38858-75
Version: 05

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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BECKMAN COULTER
Urine/CSF Albumin
Urine/CSF Albumin R2

SAFETY DATA SHEET

Document ID: B38858-75 Version 05
Revision Date (year/month/day) 2020/07/28
Last Revision Date (year/month/day) 2018/08/22

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER
Urine/CSF Albumin Calibrator Levels 1-5

SAFETY DATA SHEET

Document ID: B38859-75 Version 04
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Urine/CSF Albumin Calibrator Levels 1-5

Part Number B38859

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Transparent; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Not as hazardous per EC 1272/2008 (CLP/GHS)

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards (Continued)

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been

4.3 Indication of any immediate medical attention and special treatment needed

No medical attention or treatment required.

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Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO2), dry chemical, water spray or foam.
For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

5.3 Advice for Protective Equipment

Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

DFG MAK

Sodium Azide
CAS # 26628-22-8 — 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8 — Possibility of uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8 — 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear protective clothing and impervious gloves, as appropriate.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection.

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Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	1.002 @20°C
Color	Colorless	**Solubility**	
Transparency	Transparent	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	6.3 - 6.7	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid exposure to heat and direct sunlight.
Avoid contact with incompatible materials.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg
Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	Not based on available data.
Skin Corrosion/Irritation	Not based on available data.
Serious eye damage/eye irritation	Not based on available data.
Respiratory/skin sensitization	Not based on available data.
Carcinogenicity	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not based on available data.
Reproductive Toxicity	Not based on available data.
target organ toxicity – single exposure	
	Not based on available data.
target organ toxicity – repeated exposure	
	Not based on available data.
Aspiration hazard	Not based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L -through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 123-91-1	1,4-Dioxane	0.1% de minimis concentration
CAS # 75-21-8	Ethylene Oxide	0.1% de minimis concentration
CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration
CAS # 75-56-9	Propylene Oxide	0.1% de minimis concentration

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 75-56-9	Propylene Oxide

Chemical which is known to the State of California to cause development toxicity

CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause male reproductive toxicity

CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause female reproductive toxicity

CAS # 75-21-8	Ethylene Oxide

Massachusetts Right To Know (RTK) List

CAS # 128-37-0	Butylated Hydroxytoluene
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 128-37-0	Butylated Hydroxytoluene
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

Pennsylvania Right To Know (RTK) List

CAS # 128-37-0	Butylated Hydroxytoluene
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1

Updated Section 4, 6, 8, 11 - 16.

Document version and issue/revision date

Revision Date (year/month/day) 2019/07/03

Last Revision Date (year/month/day) 2015/03/20

Document ID: B38859-75

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BECKMAN COULTER
Urine/CSF Albumin Calibrator Levels 1-5

SAFETY DATA SHEET
Document ID: B38859-75 Version 04
Revision Date (year/month/day) 2019/07/03
Last Revision Date (year/month/day) 2015/03/20

Section 16 Other Information (Continued)

Version: 04

Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Safety Data Sheet

Rev.02 July.07

1. Product identification

Product Name:	
Product code :	**UTM−RT MINI 1ML IN BULK 300PKG**
Producer/supplier:	**350C.DHI**
Address:	***COPAN ITALIA SPA***
Phone number:	***25125 Brescia -Italy− Via Perotti,10***
Fax number:	***Tel. ++ 39 0302687211***
	Fax ++ 39 030 2687206

2. Information on compounds

Chemical characterization
· **Description:** Mixture consisting of the following components.
· **Dangerous components:** Void

3. Hazards identification

Skin contact:	**Irritation**
Eye contact:	**Irritation**

4. First−aid measures

Skin contact:	**Immediately wash with water and soap and rinse thoroughly.**
Eye contact:	**Rinse opened eye for 15 minutes under running water. Then consult a doctor.**
Inhalation:	**In case of unconsciousness place patient on side position for transportation.**
Swallowing:	**Immediately call a doctor.**

5. Fire−fighting measures

Extinguishing media:	**CO2, extinguishing powder or water spray. Fight larger fires with water or alcohol resistant foam**
Protective equipment:	**Wear self−contained respitory protective device** **Wear fully protective suit**

6. Accidental release measures

Precautions:	**Wear protective equipment. Keep unprotected persons away**

7. Handling and storage

Handling:	**No special measures required**
Storage:	**Store away from oxidizing agents** **Store at 2°C - 25°C**

8. Exposure controls/personal protection

Respiratory protection:	**N\A**
Hand protection:	**Latex gloves**
Eye protection:	**N\A**
Skin protection:	**Protective work clothing (lab coat)**

9. Physical and chemical properties

Appearance/odour:	**Characteristic**
pH:	**7. 30 ± 0.20**
Density, kg/l:	**Not determined**
Melting point, °C:	**Not determined**
Boiling point, °C:	**Not determined**
Solubility:	**Insoluble**
Flash point, °C:	**Not applicable**

10. Stability and reactivity

Materials and conditions to avoid:	**No decomposition if used according to specifications**
Hazardous decomposition products:	**No dangerous decomposition products known**

11. Toxicological information

Skin contact:	**Irritant to skin and mucous membranes**
Eye contact:	**Irritating effect**
Toxicological data:	**Irritant** **The products shows the following dangers according to internally approved calculation methods for preparations**

12. Ecological information

Ecology:	**The ecological effects have not been thoroughly investigated, but currently none have been identified.**
General Notes:	**Not known to be hazardous to water.**

13. Disposal considerations

Reccomendation:	**Must adhere to state and federal regulations** **Must not be disposed of with solid waste**

14. Transport information

ADR/RID:	IMO/IMDG:	ICAO/IATA−DGR:
No	**No**	**No**

15. Regulatory information

Product related hazard informations:	The product has been classified and marked in accordance with regulations on hazardous materials

16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Copan Italia or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user.
All materials may present unknown hazards and should be used with caution.
Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
· ***Contact:*** *Technical Service Representative*

The information in this safety data sheet has been obtained from current and reliable sources. However, the data is provided without warranty, express or implied, regarding its correctness or accuracy. It is the users' responsibility to determine safe conditions for use of this product and to assume liability for loss, injury, damage, or expense resulting from improper use of this product. EN−2141−SDS−0198−test−SDS−0296

greiner bio-one Page 1 / 4	**SAFETY DATA SHEET** acc. to ISO 11014, 29 CFR 1910.1200 **VACUETTE® Z No Additive Blood Collection Tube**	greiner bio-one A AN SOP 04.03.02-090 Rev.01 Valid from: Sept 12, 2016

STATEMENT

According to the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard or the European Directives 91/155/EEC, 88/379/EEC and 67/548/EEC, this product is considered an "article" and does not require a Material Safety Data Sheet. According to the mentioned agencies, an article is an item which is formed into a specific shape or design during manufacture and which does not release or otherwise result in exposure to a hazardous chemical under normal use.

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

- **Product Name:** VACUETTE® Z No Additive Blood Collection Tube
- **Manufacturer/Supplier:**

AUSTRIA
Greiner Bio-One GmbH
Bad Haller Strasse 32
4550 Kremsmünster
Austria
Tel: (+43) 7583 6791-0
Fax: (+43) 7583 6791-1114
Email: office@at.gbo.com
Emergency phone number: (+43) 7583 6791-0

USA
Greiner Bio-One North America Inc.
4238 Capital Drive
Monroe, NC 28110
USA
Tel: (+1) 888-286-3883
FAX: (+1) 800-726-0052
Email: info@us.gbo.com
Emergency phone number: (+1) 888-286-3883

BRASIL
Greiner Bio-One Brasil
Produtos Médicos Hospitalares Ltda.
Av. Affonso Pansan no. 1.967
13473-620 Vila Bertini
Americana, São Paulo - Brasil
Tel: (+55) 19 3468-9600
Fax: (+55) 19 3468-9601
Email: info@br.gbo.com
Emergency phone number: (+55) 19 3468-9600

THAILAND
Greiner Bio-One (Thailand) Ltd.
700/172 Moo. 1 Amata Nakorn Industrial Estate
Tambon Bankao, Amphur Phanthong
Chonburi 20160
Tel: (+66) 38-465633
Fax: (+66) 38-465635
Email: office@th.gbo.com
Emergency phone number: (+66) 38-465633

- **Recommended use / restrictions of use :**
  To collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. To be used only by trained healthcare professionals according to instructions of use.

SECTION 2: HAZARDS IDENTIFICATION

- **Classification according to NFPA 704:** N/A
- **Classification according to Regulation (EC) No. 1272/2008 [EU-GHS/CLP]:** N/A
- **Classification according to EU Directives 67/548/EEC or 1999/45/EC:** N/A
- **Signal Word:** N/A
- **Hazard Statements:** N/A
- **Precautionary Statements:** N/A

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- **Description: VACUETTE PET Tube** (Polyethyleneterephthalate)
- **Chemical name:** N/A
- **CAS No.** N/A
- **Quantity of substances:** N/A

SECTION 4: FIRST AID MEASURES

- **Hazard description:** N/A
- **Acute exposure effect:** N/A
- **Skin:** N/A
- **Eyes:** N/A
- **Inhalation:** N/A
- **Ingestion:** N/A

SECTION 5: FIRE-FIGHTING MEASURES

- **Suitable extinguishing media:** Use extinguishing media appropriate for surrounding fire.
- **Protective equipment:** Firefighters should wear proper protective equipment.
- **Special hazards arising from the substance or mixture:** N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

- **Personal precautions:** N/A
- **Methods for cleaning up:** N/A
- **Methods of containment:** N/A
- **Emergency procedures:** N/A

SECTION 7: HANDLING AND STORAGE

- **Handling:**
  Advice for safe handling: N/A
  Information about protection against explosions and fires: N/A
- **Storage:**
  Requirements to be met by storerooms and receptacles: N/A
  Information about storage in one common storage facility: N/A

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- **Exposure limits:**
  OSHA PEL: N/A
  ACGIH TLV : N/A
  Other recommended limits : N/A
- **Control parameters:** N/A
- **Personal protective equipment:** N/A
  General protective and hygienic measures: N/A
  Breathing equipment: N/A
  Hand protection: N/A
  Eye protection: N/A
  Body protection: N/A
- **Special requirements for PPE:** N/A
- **Hygiene measures:** N/A
- **Appropriate engineering controls:** N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance:** N/A
  Form: N/A
  Color: N/A
- **Odor:** N/A
- **Odor Threshold:** N/A
- **PH-value:** N/A
- **Melting point / Melting range:** N/A

- **Initial boiling point / boiling range:** N/A
- **Flash point:** N/A
- **Flammability (solid, gaseous):** N/A
- **Danger of explosion:** N/A
- **Vapor pressure:** N/A
- **Density:** N/A
- **Solubility in/Miscibility w/H_2O:** N/A
- **Organic solvents:** N/A
- **Solids content:** N/A
- **Partition coefficient: n-octanol/water:** N/A
- **Auto-ignition temperature:** N/A
- **Decomposition temperature:** N/A
- **Viscosity:** N/A
- **Oxidizing properties:** N/A

SECTION 10: STABILITY AND REACTIVITY

- **Reactivity:** No data available
- **Chemical Stability:** No data available
- **Possibility of hazardous reactions:** No data available
- **Conditions to avoid:** No data available
- **Incompatible materials:** No data available
- **Hazardous decomposition products:** No data available

SECTION 11: TOXICOLOGICAL INFORMATION

- **Acute toxicity:** N/A
  Eye: N/A
  Skin: N/A
  Inhalation: N/A
  Ingestion: N/A
- **Primary irritant effect:**
  On the skin: Not established
  On the eye: Not established
- **Sensitization:** Not established
- **Additional toxicological information:** None identified

SECTION 12: ECOLOGICAL INFORMATION

- **Ecotoxilogical effects:** No data is available on the adverse effects of this material on the environment.
- **Other information:** N/A
- **General notes:** N/A

SECTION 13: DISPOSAL CONSIDERATION

- **Product: Recommendation**
  Disposal should be done in accordance with all federal, state and local environmental regulations. This product is not a hazardous waste according to local regulations.
- **Packaging: Recommendation**
  Disposal should be done in accordance with all federal, state and local environmental regulations. This product is not a hazardous waste according to local regulations.

SECTION 14: TRANSPORT INFORMATION

- **DOT regulations:** Not regulated
- **Land transport ADR/RID:** Not regulated

- **Maritime transport IMDG:** Not regulated
- **Air transport ICAO-TI and IATA-DGR:** Not regulated

SECTION 15: REGULATORY INFORMATION

- **OSHA, 29 CFR 1910.1200(g) and Appendix D. United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), third revised edition, United Nations, 2009**
- **EC directives: 91/155/EEC, 93/112/EC, 88/379/EEC**
- **Water hazard class:** N/A
- **Note:** Please note that there may be additional legal provisions to be observed. We recommend that you keep yourself informed about all applicable international, national and local regulations.

SECTION 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, neither Greiner Bio-One nor any of its subcontractors or suppliers assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010 and 29 CFR § 1910.1200

Revision date: 11/05/2017 Supersedes: 25/07/2016 Version: 11.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
Name	:	VALIDATE® Calibration Verification Test Kit
Product code	:	203, 301, 306, 307, 308, 401, 402, 406, 407, 501, 502, 504, 506, 601, 602, 703, 901, 1100, 1300, 1400au, 1400ri

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/preparation	:	Intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Maine Standards Company, LLC
221 US Route 1
Cumberland Foreside, ME 04110 - USA
800-377-9684; 207-892-1300 Hours: 8:30 AM to 5:00 PM, Eastern Time, Monday through Thursday. 8:30 AM to 4:00 PM on Friday.

1.4. Emergency telephone number

Emergency number	:	Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Maine Standards Company LLC customer number 798037. Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified.

Full text of H-phrases: see section 16.

Classification according to Directive 67/548/EEC or 1999/45/EC [DPD]

Not classified.

Full text of R-phrases: see section 16.

Classification according to 2012 29 CFR § 1910.1200 (OSHA-GHS)

Not classified.

Classification according to WHMIS (Controlled Products Regulations)

Not classified.

Adverse physicochemical, human health and environmental effects

None under normal conditions. However, product does contain material of human origin and should be considered potentially infectious.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)	:	No symbol required
Signal word (CLP)	:	Not Applicable
Hazard statements (CLP)	:	Not Applicable
Precautionary statements (CLP)	:	Not Applicable
EUH phrases	:	Not Applicable

Labelling according to 2012 29 CFR § 1910.1200 [OSHA]

Hazard pictograms (OSHA)	:	No symbol required
Signal word (OSHA)	:	Not Applicable
Hazard statements (OSHA)	:	Not Applicable
Precautionary statements (OSHA)	:	Not Applicable

2.3. Other hazards

Each human donor used in the preparation of the product was tested and found non-reactive for Anti-HIV I/II, Anti-HCV, and HbsAg, with kits approved by the United States FDA.

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010 and 29 CFR § 1910.1200

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Human Serum Albumin	(CAS No.) 70024-90-7 EINECS:274-272-6	60-100		

Additional information: Contains human sourced and/or potentially infectious material.

Full text of R-, H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If symptoms are experienced remove source of contamination or move victim to fresh air. Obtain medical advice.

First-aid measures after skin contact : No health effects expected. If irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

First-aid measures after eye contact : No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the chemical is removed. If irritation persists, obtain medical advice.

First-aid measures after ingestion : If irritation or discomfort occurs, obtain medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : Overexposure to mists or spray may produce slight irritation of the respiratory system.

Symptoms/injuries after skin contact : May cause slight irritation to the skin.

Symptoms/injuries after eye contact : May cause slight irritation to eyes.

Symptoms/injuries after ingestion : May cause gastric irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: : Powder, alcohol-resistant foam, water spray, carbon dioxide.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No particular fire or explosion hazard. In case of fire it can release carbon oxides, nitrogen oxides, hydrogen chloride and/or chlorine gases, disodium oxide and other toxic and irritating fumes.

Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Advice for firefighters

Protective equipment for firefighters : In case of fire: Wear self-contained breathing apparatus. Wear recommended personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing, gloves and eye/face protection.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye/face protection.

Emergency procedures : Avoid all eye and skin contact and do not breathe spray and mist. Prevent product from entering drains.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

Methods for cleaning up : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect all waste in suitable and labelled containers and dispose according to local legislation.

6.4. Reference to other sections

Refer to sections 8 and 13.

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010 and 29 CFR § 1910.1200

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	:	Avoid all unnecessary exposure. Handle as if potentially infectious.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures:	:	Provide local exhaust or general room ventilation.
Storage condition(s)	:	Keep container tightly closed and dry. Store in well ventilated area. Keep cool.
Incompatible materials	:	None Known

7.3. Specific end use(s)

Intended for in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

None

8.2. Exposure controls

Appropriate engineering controls	:	Either local exhaust or general room ventilation is usually required.
Personal protective equipment	:	Gloves. Safety glasses.

Hand protection	:	If this material may come in contact with the hands during handling and use, we recommend wearing gloves of the following material(s): natural rubber latex, neoprene, nitrile, or polyvinyl chloride (PVC). Consult your PPE provider for breakthrough times and the specific glove that is best for you based on your use patterns.
Eye protection	:	As a minimum, safety glasses with side shields should be worn when handling this material
Skin and Body protection	:	If this material may come into contact with the body during handling and use, we recommend wearing appropriate protective clothing to prevent contact with the skin.
Respiratory protection	:	With correct and proper use, and under normal conditions, breathing protection is not required
Environmental exposure controls	:	None known.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless to slightly yellow
Odour	:	No data available
Odour threshold	:	No data available
pH	:	No data available
Melting point	:	No data available
Solidification point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Flammability (solid, gas)	:	Not applicable.
Explosive limits	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	Water: Soluble in water
Log Pow	:	No data available
Log Kow	:	No data available
Self ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	Not explosive.
Oxidising properties	:	Not oxidizing.

9.2. Other information

Upper flammable Limit	:	No Data Available
Lower Flammable Limit	:	No Data Available
Sensitivity to mechanical impact	:	No Data Available
Sensitivity to static discharge	:	No Data Available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Entry	:	Skin, Eyes, Inhalation and Ingestion
Acute toxicity	:	(Mixture not tested. Based on available data.)

Human Serum Albumin CAS#70024-90-7	
No data available	

Skin corrosion/irritation	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Serious eye damage/irritation	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	:	May cause an allergic skin reaction (Mixture not tested. Based on available data.)
Germ cell mutagenicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Carcinogenicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met). No ingredient present at greater than 0.1% is listed in National Toxicology Program (NTP) Report on Carcinogens (12th Edition), the International Agency for Research on Cancer (IARC) Monographs (Volumes 1–105), or by OSHA.
Reproductive toxicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Teratogenicity/Embryotoxicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Specific target organ toxicity (single exposure)	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Specific target organ toxicity (repeated exposure)	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Aspiration hazard	:	Not classified (Not applicable)
Potential Adverse human health effects and symptoms	:	May cause slight temporary irritation.
Toxicologically Synergistic Materials	:	None known

SECTION 12: Ecological information

12.1. Toxicity

None

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

None

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

VALIDATE® Calibration Verification Test Kit
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

12.6. Other adverse effects

No additional information available

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010 and 29 CFR § 1910.1200

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of this material and its container at hazardous or special waste collection point. Can be deposited in landfills, sent to an incineration or other appropriate means of disposal provided they meet the requirements of local laws. Comply with applicable local, national and international regulation.

SECTION 14: Transport information

Not regulated for transport.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH candidate substance

15.1.2. National regulations

Regional legislation : Canada: This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

CAS#70024-90-7 is not listed on Canada's DSL List or Ingredient Disclosure List

USA: This product has been classified in accordance with the 2012 hazard criteria of the *Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS)* and the SDS contains all the information required by the 29 CFR § 1910.1200.

15.2. Chemical safety assessment

CSA has not been established

SECTION 16: Other information

Sources of Key data : Data arise from reference works and literature.

Abbreviations and acronyms : WHMIS – Workplace Hazardous Material Information System
CFR - Code of Federal Regulations
CLP - Classification, Labelling and Packaging
CSA – Chemical Safety Assessment
DPD – Dangerous Products Directive
EC - European Community
EC No. - European Commission number
EEC - European Economic Community
EN - European Norm
EU- European Union
GHS – Globally Harmonized System
h – hours
H-phrases – Hazard phrases
Log Pow – Log of the Octanol/Water Partition Coefficient
MSDS – Material Safety Data Sheet
No. – Number
OSHA - Occupational Safety and Health Administration
PBT - Persistent, Bioaccumulative and Toxic substance
PPE – Personal Protective Equipment
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals
R-phrases – Risk phrases
SDS – Safety Data Sheet
vPvB - Very Persistent and Very Bioaccumulative
WHMIS – Workplace Hazardous Material Information System

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

05/06/2019

Kit Components

Product code	Description
12000447 **2702455** **2702455EX**	**Variant II Turbo HbA1c Kit**

Components:

2702456	Variant II Turbo HbA1c Kit 2.0 Elution Buffer A
2702457	Variant II Turbo HbA1c Kit 2.0 Elution Buffer B
2702459	Variant II Turbo HbA1c Kit 2.0 Calibrator 1
2702460	Variant II Turbo HbA1c Kit 2.0 Calibrator 2
2702462	Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 04/16/2019

1 Identification

· **Product identifier**

· **Trade name:** **Variant II Turbo HbA1c Kit 2.0 Elution Buffer A**

· **Catalog or product number:** 2702456
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Void
· **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.

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Safety Data Sheet
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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

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· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Dilute with plenty of water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
26628-22-8 sodium azide	
REL (United States)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (United States)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

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· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:**
Not required.
Not necessary if room is well-ventilated. Adequate ventilation required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	6
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard. Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

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· **Partition coefficient (n-octanol/water):** Not determined.	
· **Viscosity:**	
dynamic at 20 °C:	0.952 mPas
kinematic:	Not determined.
· **Solvent content:**	
Water:	99.2 %
Solids content:	0.3 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

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*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
Perchlorate material - special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

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· **UN "Model Regulation":** Void

*
15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7601-89-0	sodium perchlorate
26628-22-8	sodium azide
110-15-6	succinic acid
7732-18-5	water

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

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Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Date of preparation / last revision** *05/06/2019 / -*

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health

· **** Data compared to the previous version altered.***

BIO-RAD

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 04/16/2019

1 Identification

· **Product identifier**

· **Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B**

· **Catalog or product number:** 2702457
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**			
7601-89-0	sodium perchlorate	Ox. Sol. 1, H271 Acute Tox. 4, H302	1-2.5%

· **Additional information** For the wording of the listed risk phrases refer to section 15.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet
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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 1)

*
5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:**
Do not allow to penetrate the ground/soil.
Dilute with plenty of water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**		
sodium perchlorate		6.3 mg/m³
· **PAC-2:**		
7601-89-0	sodium perchlorate	69 mg/m³
· **PAC-3:**		
7601-89-0	sodium perchlorate	420 mg/m³

*
7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 2)

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
26628-22-8 sodium azide	
REL (United States)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (United States)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:**
Not required.
Not necessary if room is well-ventilated. Adequate ventilation required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	6.7
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard. Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

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· **Vapor pressure at 20 °C:**	23 hPa
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with Water:**	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic at 20 °C:	0.952 mPas
kinematic:	Not determined.
· **Solvent content:**	
Water:	98.1 %
Solids content:	1.3 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

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· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
Perchlorate material - special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void

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Safety Data Sheet
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Printing date 05/06/2019 Reviewed on 04/16/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 5)

· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	Void

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7601-89-0	sodium perchlorate
26628-22-8	sodium azide
110-15-6	succinic acid
7732-18-5	water

· **TSCA new (21st Century Act)**

7601-89-0	sodium perchlorate	ACTIVE/EXEMPT

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

7601-89-0	sodium perchlorate	NL

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 6)

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 05/06/2019 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Ox. Sol. 1: Oxidizing solids – Category 1
Acute Tox. 4: Acute toxicity – Category 4
· ***** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

*
1 Identification

· **Product identifier**

· **Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1**

· **Catalog or product number:** 2702459
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Classification system**
· **Special Hazards** Contains human sourced and/or potentially infectious components.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**		
57-50-1	sucrose, pure	10-20%

· **Additional information**
Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 1)

· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

*
7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 2)

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
57-50-1 sucrose, pure	
PEL (United States)	Long-term value: 15* 5** mg/m³ *total dust **respirable fraction
REL (United States)	Long-term value: 10* 5** mg/m³ *total dust **respirable fraction
TLV (United States)	Long-term value: 10 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
Synthetic gloves
· **For the permanent contact gloves made of the following materials are suitable:** Synthetic gloves
· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Synthetic gloves
· **As protection from splashes gloves made of the following materials are suitable:** Synthetic gloves
· **Eye protection:** Safety glasses

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Color:	Red
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.

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Safety Data Sheet
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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 3)

· **Danger of explosion:**	Product does not present an explosion hazard. Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Insoluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Water:	1.0 %
Solids content:	99.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 4)

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

*
14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void

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Safety Data Sheet
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· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	Void

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

57-50-1	sucrose, pure
7732-18-5	water

· **TSCA new (21st Century Act)**

57-50-1	sucrose, pure	ACTIVE/EXEMPT

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**

32986-56-4	tobramycin
1405-41-0	Gentamicin Sulfate

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

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· **TLV (Threshold Limit Value established by ACGIH)**		
57-50-1	sucrose, pure	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 05/06/2019 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· ***** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

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*
1 Identification

· **Product identifier**

· **Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2**

· **Catalog or product number:** 2702460
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Classification system**
· **Special Hazards** Contains human sourced and/or potentially infectious components.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**		
57-50-1	sucrose, pure	10-20%

· **Additional information**
Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 1)

· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

*
7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 2)

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
57-50-1 sucrose, pure	
PEL (United States)	Long-term value: 15* 5** mg/m³ *total dust **respirable fraction
REL (United States)	Long-term value: 10* 5** mg/m³ *total dust **respirable fraction
TLV (United States)	Long-term value: 10 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
Synthetic gloves
· **For the permanent contact gloves made of the following materials are suitable:** Synthetic gloves
· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Synthetic gloves
· **As protection from splashes gloves made of the following materials are suitable:** Synthetic gloves
· **Eye protection:** Safety glasses

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Color:	Red
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 3)

· **Danger of explosion:**	Product does not present an explosion hazard. Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Water:	1.0 %
Solids content:	99.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 4)

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

*
14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Void

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Safety Data Sheet
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(Contd. of page 5)

· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	Void

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

57-50-1	sucrose, pure
7732-18-5	water

· **TSCA new (21st Century Act)**

57-50-1	sucrose, pure	ACTIVE/EXEMPT

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**

32986-56-4	tobramycin
1405-41-0	Gentamicin Sulfate

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

(Contd. on page 7)

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acc. to OSHA HCS

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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 6)

· **TLV (Threshold Limit Value established by ACGIH)**		
57-50-1	sucrose, pure	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 05/06/2019 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· ***** Data compared to the previous version altered.**

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

1 Identification

· **Product identifier**

· **Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge**

· **Catalog or product number:** 2702462
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:** TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Void
· **Additional information** For the wording of the listed risk phrases refer to section 15.

*
4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 2)

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Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 1)

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

*
7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

(Contd. on page 3)

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acc. to OSHA HCS

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Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 2)

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Granulate
Color:	Whitish
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· **Flash point:**	Not applicable Not determined.
· **Flammability (solid, gaseous)**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard. Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density at 20 °C:**	1.02938 g/cm³
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Insoluble
· **Partition coefficient (n-octanol/water):**	Not determined.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

(Contd. of page 3)

· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Water:	2.0 %
Solids content:	98.0 %
· **Other information**	No further relevant information available.

*
10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 4)

· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

*
14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	Void

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 Reviewed on 05/06/2019

Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 5)

*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
None of the ingredients is listed.

· **Section 313 (40CFR372.65):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
7732-18-5 water

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
The product does not contain listed components.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Developmental Toxicity**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 05/06/2019 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/06/2019 *Reviewed on 05/06/2019*

Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 6)

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
· **** Data compared to the previous version altered.***

SAFETY DATA SHEET

Virex TB Ready-To-Use Disinfectant Cleaner

Version Number: 1 **Preparation date:** 2014-10-09

1. IDENTIFICATION

Product name: Virex TB Ready-To-Use Disinfectant Cleaner
Product Code: 04743
SDS #: MS0800547
Recommended use:
- Industrial/Institutional
- Disinfectant
- This product is intended to be used neat.

Uses advised against: Uses other than those identified are not recommended

Manufacturer, importer, supplier:
US Headquarters
Diversey, Inc.
8310 16th St.
Sturtevant, Wisconsin 53177-1964
Phone: 1-888-352-2249
MSDS Internet Address: www.diversey.com

Canadian Headquarters
Diversey, Inc. - Canada
3755 Laird Road
Mississauga, Ontario L5L 0B3
Phone: 1-800-668-3131

Emergency telephone number: 1-800-851-7145 (U.S.); 1-651-917-6133 (Int'l)

2. HAZARDS IDENTIFICATION

Classification for the undiluted product
Serious eye damage/eye irritation Category 2A

Signal Word: **Warning**

Precautionary Statements
CAUSES SERIOUS EYE IRRITATION.
Avoid contact with eyes, skin and clothing. Wash affected areas thoroughly after handling. May cause irritation to mouth, throat and stomach. Wear chemical-splash goggles and chemical-resistant gloves. IF SWALLOWED: Rinse mouth. Drink a cupful of milk or water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. If eye irritation persists: Get medical advice or attention. Dispose of in accordance with all federal, state and local applicable regulations. SUPPLEMENTAL INFORMATION. May be mildly irritating to skin. In case of contact, immediately flush with plenty of water. If irritation occurs and persists, get medical attention.

Health hazards not otherwise classified (HHNOC) - Not applicable
Physical hazards not otherwise classified (PHNOC) - Not applicable

Classification for the diluted product @ RTU
This product is intended to be used neat.

Precautionary Statements
See undiluted product information above.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Classified Ingredients

Ingredient(s)	CAS #	Weight %
Diethylene glycol butyl ether	112-34-5	5 - 10%
Tetrasodium salt of EDTA	64-02-8	1% - < 3%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	> 0.1% - < 1%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	> 0.1% - < 1%

*Exact percentages are being withheld as trade secret information

4. FIRST AID MEASURES

Undiluted Product:

Eyes: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. If eye irritation persists: Get medical advice/attention.
Skin: In case of contact, immediately flush with plenty of water. If irritation occurs and persists, get medical attention.
Inhalation: No specific first aid measures are required.
Ingestion: IF SWALLOWED: Rinse mouth. Drink a cupful of milk or water.

Most Important Symptoms/Effects: No information available.
Immediate medical attention and special treatment needed Not applicable.
Aggravated Medical Conditions: Persons with pre-existing skin disorders may be more susceptible to irritating effects.

Diluted Product:
This product is intended to be used neat.

Eyes: See undiluted product information above.
Skin: See undiluted product information above.
Inhalation: See undiluted product information above.
Ingestion: See undiluted product information above.

5. FIRE-FIGHTING MEASURES

Specific methods: No special methods required
Suitable extinguishing media: The product is not flammable. Extinguish fire using agent suitable for surrounding fire.
Specific hazards: Not applicable.

Special protective equipment for firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Extinguishing media which must not be used for safety reasons: No information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Put on appropriate personal protective equipment (see Section 8.).
Environmental precautions and clean-up methods: Clean-up methods - large spillage. Soak up with inert absorbent material. Sweep up and shovel into suitable containers for disposal. Use a water rinse for final clean-up.

7. HANDLING AND STORAGE

Handling: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Do not taste or swallow. FOR COMMERCIAL AND INDUSTRIAL USE ONLY.

Storage:
Protect from freezing. Keep tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.
Aerosol Level (if applicable) : Not applicable

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines: .

Ingredient(s)	CAS #	ACGIH	OSHA
Diethylene glycol butyl ether	112-34-5	10 ppm (TWA)	-
Tetrasodium salt of EDTA	64-02-8	-	-
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	-	-
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	-	-

Undiluted Product:

Engineering measures to reduce exposure:
No special ventilation requirements General room ventilation is adequate

Personal Protective Equipment

Eye protection: Chemical-splash goggles.
Hand protection: Chemical-resistant gloves.
Skin and body protection: No special requirements under normal use conditions.
Respiratory protection: No special requirements under normal use conditions.
Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Diluted Product:

This product is intended to be used neat.

Personal Protective Equipment

Eye protection: Chemical-splash goggles.
Hand protection: Chemical-resistant gloves.
Skin and body protection: No special requirements under normal use conditions.
Respiratory protection: No special requirements under normal use conditions.
Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid
Evaporation Rate: No information available
Odor threshold: No information available.
Melting point/range: Not determined
Autoignition temperature: No information available
Solubility in other solvents: No information available
Density: 8.44 lbs/gal 1.012 Kg/L
Bulk density: No information available
Flash point: > 200 °F > 93.3 °C
Dilution Flash Point: > 200 °F > 93.3 °C
Elemental Phosphorus: 0 % by wt.
pH: 12.2
Dilution pH: 12.2 @ RTU
Metal Corrosion: Not determined
Explosion limits: - upper: Not determined **- lower:** Not determined

Color: Clear, Colorless
Odor: Lemon Citrus
Boiling point/range: Not determined
Decomposition temperature: Not determined
Solubility: Completely Soluble
Relative Density (relative to water): 1.012
Vapor density: No information available
Vapor pressure: No information available.
Partition coefficient (n-octanol/water): No information available
Viscosity: No information available
VOC: 0.06 % *
VOC % by wt. at use dilution 0.06 % *
Flammability (Solid or Gas): Not applicable

* - Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 2, Consumer Products, Sections 94508

10. STABILITY AND REACTIVITY

Reactivity: Not Applicable
Stability: The product is stable
Hazardous decomposition products: Nitrogen oxides (NOx).
Materials to avoid: Acids. Oxidizing agents.
Conditions to avoid: No information available.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
Eye contact, Skin contact, Inhalation

Delayed, immediate, or chronic effects and symptoms from short and long-term exposure
Skin contact: May be mildly irritating to skin. Symptoms may include redness and/or transient discomfort.
Eye contact: Causes serious eye irritation. Symptoms may include pain, redness, and watering.
Ingestion: May be irritating to mouth, throat and stomach. Symptoms may include stomach pain and nausea.
Inhalation: May be irritating to nose, throat, and respiratory tract. Symptoms may include coughing and difficulty breathing.
Sensitization: No known effects.

Numerical measures of toxicity

ATE - Oral (mg/kg):	>5000
ATE - Inhalatory, mists (mg/l):	>20

12. ECOLOGICAL INFORMATION

Ecotoxicity: No information available.

Persistence and Degradability: No information available.

Bioaccumulation: No information available.

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: PESTICIDAL WASTE - Observe all applicable Federal/Provincial/State regulations and Local/Municipal ordinances regarding disposal of pesticide wastes. This product, as sold, if discarded or disposed, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Dispose in compliance with all Federal, state, provincial, and local laws and regulations.
Contaminated Packaging: Do not re-use empty containers.
RCRA Hazard Class (undiluted product): Not Regulated

14. TRANSPORT INFORMATION

DOT/TDG/IMDG: Please refer to the Diversey HazMat Library, only available through Internet Explorer, http://naextranet.diversey.com/dot/, for up to date shipping information.

DOT (Ground) Bill of Lading Description: DISINFECTANTS

IMDG (Ocean) Bill of Lading Description: DISINFECTANTS

15. REGULATORY INFORMATION

International Inventories at CAS# Level
All components of this product are listed on the following inventories: U.S.A. (TSCA).

U.S. Regulations
EPA Reg. No. : 70627-2
This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.
ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic invertebrates.

California Proposition 65: This product is not subject to the reporting requirements under California's Proposition 65.

RIGHT TO KNOW (RTK)

Ingredient(s)	CAS #	MARTK:	NJRTK:	PARTK:	RIRTK:
Water	7732-18-5	-	-	-	-
Diethylene glycol butyl ether	112-34-5	-	X	-	-
Tetrasodium salt of EDTA	64-02-8	-	-	-	-
Alcohol ethoxylates	68131-39-5	-	-	-	-
Sodium metasilicate	6834-92-0	-	-	-	-
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	-	-	-	-
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	-	-	-	-

CERCLA/ SARA

Ingredient(s)	CAS #	Weight %	CERCLA/SARA RQ (lbs)	Section 302 TPQ (lbs)	Section 313
Diethylene glycol butyl ether	112-34-5	5 - 10%			X

Ingredient(s)	CAA HAP	CAA ODS	CWA Priority Pollutants
Diethylene glycol butyl ether	X		

SARA 311/312 Hazard Categories

Immediate: x
Delayed: -
Fire: -
Reactivity: -
Sudden Release of Pressure: -

Canada

WHMIS hazard class: Not for sale in Canada.

Ingredient(s)	CAS #	NPRI
Diethylene glycol butyl ether	112-34-5	X

16. OTHER INFORMATION

NFPA (National Fire Protection Association)
Rating Scale: (Low Hazard) 0 - 4 (Extreme Hazard)

Health 2
Flammability 0
Instability 0

Version Number: 1
Preparation date: 2014-10-09

Reason for revision: Not applicable
Prepared by: NAPRAC
Additional advice: • Contains an added fragrance, see "Odor" heading in section 9 for specific description

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Kit SDS Cover Sheet

Doc. ID: B68736-75: Rev. AA
Issued (year/month/day) 2016/12/13

Product Information

Product Name $1,25(OH)_2$ Vitamin D ELISA

Part Number B68736

Additional Product Information

This kit contains a microtiter plate that is considered an article and thereby exempt from SDS requirements.
For In Vitro Diagnostic Use. See product literature for details.

Components

Description

Incubation buffer
Elution solution
Concentrated conjugate
Concentrated HRP
Conjugate buffer
Calibrators
Controls
Wash solution
TMB chromogen solution
Stop solution

Transport Information

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	3316	3316	3316	3316	3316
Shipping Name	Chemical kit				
Hazard Class	9 Miscellaneous Dangerous Goods	9 Miscellaneous dangerous substances and articles	9 Miscellaneous hazardous material	9 Miscellaneous dangerous substances and articles	9 Miscellaneous Dangerous Goods
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	M11	Not applicable
Packing Group	II	II	II	II	II
Special Provisions	A44; A163	251; 340	15	251, 340	65, 141
Additional information					
IATA ERG Code	9L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-A, S-P	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	171	Not applicable	171

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Transport Information (Continued)

Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for user

No special precautions for users are required.

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Global SDS – English

BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Incubation buffer

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

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Section 3 Composition and Information on Ingredients (Continued)

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment — Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information — No further relevant information available.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions	Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.
6.2 Environmental Precautions	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4 Reference to other sections	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling	Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses	No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.00 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not applicable	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

May cause sensitization by skin contact.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

No information available.

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

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Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Borate Decahydrate is listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK Sodium Borate Decahydrate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Borate Decahydrate
Boric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

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Section 16 Other Information (Continued)

T - Toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System

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Section 16 Other Information (Continued)

vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Elution solution

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Flammable Liquids, Category 2
Acute Toxicity Oral, Category 3
Acute Toxicity Inhalation, Category 3
Acute Toxicity Dermal, Category 3
Specific Target Organ Toxicity Single Exposure Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Flammable Liquids, Category 2
Acute Toxicity Dermal, Category 3
Acute Toxicity Oral, Category 3
Acute Toxicity Inhalation, Category 3
Specific Target Organ Toxicity Single Exposure Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Methanol

Pictogram

Signal Word

DANGER

Hazard Statements

H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H370 Causes damage to organs.
H331 Toxic if inhaled.
H311 Toxic in contact with skin.

Precautionary Statements

P210 Keep away from heat, hot surfaces, and sparks. No smoking.
P501 Dispose of contents/container in accordance with local/national regulations
P240 Ground container and receiving equipment.
P241 Use explosion-proof electrical equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharge.
P261 Avoid breathing vapours.
P270 Do no eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P308+P311 If exposed or concerned: Call a doctor/physician.
P311 Call a POISON CENTER or doctor/physician.
P330 Rinse mouth.
P361+P364 Take off immediately contaminated clothing and wash it before use
P370+P378 In case of fire: Use water spray for extinction.

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Section 2 Hazards Identification (Continued)

P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
P233 Keep container tightly closed.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Methanol CAS # 67-56-1 EINECS # 200-659-6 Index # 603-001-00-X	100	F;R11 T;R23/24/25-39/23/24/25	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Flam. Liq. 2 STOT SE 1 H225; H301; H311; H331; H370	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. Do not induce vomiting or give anything by mouth. Obtain medical attention immediately.

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Section 4 First Aid Measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

Toxic if swallowed.
Toxic in contact with skin.
Toxic if inhaled.
Causes damage to organs.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

Dry chemical, carbon dioxide or alcohol-resistant foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

Highly flammable liquid and vapour.

Hazardous Combustion Products

No further relevant information available.

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Avoid inhaling, ingesting, and contact with eyes and skin.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration or evaporation.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Use in well ventilated area away from heat or ignition sources.

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Section 7 Handling and Storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA

ACGIH

Methanol CAS # 67-56-1	250 ppm STEL; 200 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route

DFG MAK

Methanol CAS # 67-56-1	skin notation; 800 ppm Peak; 1080 mg/m3 Peak; 200 ppm TWA MAK; 270 mg/m3 TWA MAK

Ireland

Methanol CAS # 67-56-1	200 ppm TWA; 260 mg/m3 TWA; 600 ppm STEL (calculated); 780 mg/m3 STEL (calculated); Potential for cutaneous absorption

IOELVs

Methanol CAS # 67-56-1	Possibility of significant uptake through the skin; 200 ppm TWA; 260 mg/m3 TWA

NIOSH

Methanol CAS # 67-56-1	6000 ppm IDLH; 250 ppm STEL; 325 mg/m3 STEL; 200 ppm TWA; 260 mg/m3 TWA

Japan

Methanol CAS # 67-56-1	200 ppm OEL; 260 mg/m3 OEL

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

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Section 8 Exposure Controls and Personal Protection (Continued)

Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	0.79 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	470°C (878°F)
Boiling Point	64.5°C (148.1°F)	**Decomposition Temperature**	Not determined
Flash Point	11.5°C (52.7°F)	**Percent Volatiles**	Not determined
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not determined	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Methanol 3.05 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

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Global SDS – English

Section 10 Stability and Reactivity (Continued)

10.5 Incompatible materials Reducing Reagent

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Methanol
CAS # 67-56-1 — Inhalation LC50 Rat 22500 ppm 8 h; Oral LD50 Rat 6200 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation Not classified based on available data.

Serious eye damage/eye irritation Not classified based on available data.

Respiratory/skin sensitization Not classified based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not classified based on available data.

Reproductive Toxicity Not classified based on available data.

Specific target organ toxicity – single exposure

May cause damage to organs.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

Other Information

Toxic if swallowed.
Toxic in contact with skin.
Toxic if inhaled.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Methanol
CAS # 67-56-1 — 96 h LC50 Pimephales promelas: 28200 mg/L [flow-through]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 19500 - 20700 mg/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 18 - 20 mL/L [static]; 96 h LC50 Lepomis macrochirus: 13500 - 17600 mg/L [flow-through]

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Section 12 Ecological Information (Continued)

	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	**UN/ID Number**	1230	1230	1230	1230	PIN - 1230
14.2	**Shipping Name**	Methanol Solution				
14.3	**Hazard Class**	3 Flammable Liquids	3 Flammable liquids	3 Flammable liquid	3 Flammable Liquids	3 Flammable Liquids
	Subsidiary Risk	6.1 Toxic substances	6.1 Toxic substances	6.1 Poisonous materials	6.1 Toxic substances	6.1 Toxic substances
	Classification Code	Not applicable	Not applicable	Not applicable	FT1	Not applicable
14.4	**Packing Group**	II	II	II	II	II
	Special Provisions	A104; A113	279	Not applicable	279	43
	Additional information					
	IATA ERG Code	3P	Not applicable	Not applicable	Not applicable	Not applicable

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Section 14 Transport Information (Continued)

EmS	Not applicable	F-E, S-D	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	131	Not applicable	131

14.5 Environmental Hazards

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Flammable and toxic liquid.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Methanol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Methanol is listed.

California Proposition 65 Methanol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL Methanol is listed.

New Jersey Dept. of Health RTK List

Methanol is listed.

Pennsylvania RTK Methanol is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1230

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Methanol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 3** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Hazard Class, hazard statements and risk phrase description from section 3

F - Highly flammable
T - Toxic
R11 Highly flammable.
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Flam. Liq. 2 - Flammable Liquids, Category 2
STOT SE 1 - Specific Target Organ Toxicity Single Exposure Category 1
H225 - Highly flammable liquid and vapour.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H331 - Toxic if inhaled.
H370 - Causes damage to organs.
H370 - Causes damage to organs (Respiratory system)
H370 - Causes damage to organs (Liver and Kidney)
H370 - Causes damage to organs (Kidney)
H370 - Causes damage to organs (Liver)

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Concentrated conjugate

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

Not classified based on available data.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

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Section 12 Ecological Information (Continued)

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	New document	

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Concentrated HRP

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact

In case of skin contact, rinse with water as a precaution.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Yellowish	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	6.05	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not applicable	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

Not classified based on available data.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

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Section 12 Ecological Information (Continued)

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	New document	

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Conjugate buffer

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.00 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.4	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
	Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Not classified based on available data.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.

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Section 11 Toxicological Information (Continued)

Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity – single exposure	
	Not classified based on available data.
Specific target organ toxicity – repeated exposure	
	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

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Section 15 Regulatory Information (Continued)

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T - Toxic

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H331 - Toxic if inhaled.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Calibrators

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

White; Opaque; Lyophilized Powder; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.

If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH None established

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	White	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	Not applicable	**Partition coefficient: n-octanol/water**	Not applicable
Melting Point	Not determined	**Auto-ignition Temp.**	Not determined
Boiling Point	Not applicable	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not applicable	**Vapor Pressure**	Not applicable
Flammability (Solid, Gas)	Not determined	**Viscosity**	Not applicable
Flammability Limits	Not determined	**Explosive Properties**	Not applicable
Vapor Density	Not applicable	**Oxidizing Properties**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

	Odor Threshold	Not applicable
9.2	**Other Information**	No further relevant information available.

Section 10 Stability and Reactivity

10.1	**Reactivity**	No further relevant information available.
10.2	**Chemical Stability**	The product is stable in accordance with recommended storage conditions.
10.3	**Possibility of hazardous reactions**	No further relevant information available.
10.4	**Conditions to Avoid**	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5	**Incompatible materials**	No further relevant information available.
10.6	**Hazardous Decomposition Products**	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	Not classified based on available data.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	May cause sensitization by skin contact.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

Other Information This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.
Microtox No information available.
Water Flea No information available.
Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 Gentamicin Sulfate has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Controls

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Opaque; Lyophilized Powder; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 CLP/GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P501 Dispose of contents/container in accordance with local/national regulations
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	<0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.

If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder	**Specific Gravity (Water=1.0)**	1.02 @20°C
Color	Colorless	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	Not applicable	**Partition coefficient: n-octanol/water**	Not applicable
Melting Point	Not determined	**Auto-ignition Temp.**	Not determined
Boiling Point	Not applicable	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not applicable	**Vapor Pressure**	Not applicable
Flammability (Solid, Gas)	Not determined	**Viscosity**	Not applicable
Flammability Limits	Not determined	**Explosive Properties**	Not applicable
Vapor Density	Not applicable	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Oral LD50 Rat 53 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation Not classified based on available data.

Serious eye damage/eye irritation Not classified based on available data.

Respiratory/skin sensitization May cause sensitization by skin contact.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity – single exposure	
	Not classified based on available data.
Specific target organ toxicity – repeated exposure	
	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other Information	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	No ingredients listed.
CERCLA RG's, 40 CFR 302.4	No ingredients listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.
Pennsylvania RTK	No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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Section 15 Regulatory Information (Continued)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Physical Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms	ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Wash solution

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Whitish; Opaque; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	<0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

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Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK	
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs	
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.3 mg/m3 STEL; 0.1 mg/m3 TWA
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.06 @20°C
Color	Whitish	**Solubility**	
Transparency	Opaque	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	7.5 - 8.5	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg

Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Not classified based on available data.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity – single exposure	
	Not classified based on available data.
Specific target organ toxicity – repeated exposure	
	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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		To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

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Section 15 Regulatory Information (Continued)

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name TMB chromogen solution

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Clear; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact If product enters eyes, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear protective clothing and impervious gloves, as appropriate.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	0.98 @20°C
Color	Clear	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	5.0 - 6.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not applicable	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

Not classified based on available data.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity – single exposure

Not classified based on available data.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species No information available.

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

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Section 12 Ecological Information (Continued)

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number: Not regulated for transportation

14.2 Shipping Name: Not regulated for transportation

14.3 Hazard Class: Not regulated for transportation

14.4 Packing Group: Not regulated for transportation

14.5 Environmental Hazards: Not regulated for transportation

14.6 Special Precautions for user: None

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313 No ingredients listed.

CERCLA RG's, 40 CFR 302.4 No ingredients listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 1** **Reactivity with Water: 0** **Physical Contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	New document	

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: B68736-75 Rev. AA
Issued (year/month/day) 2016/12/13

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Stop solution

Part Number Component of P/N B68736

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IMMUNOTECH s.r.o.
Radiová 1
102 27 Prague 10
Czech Republic
Tel. +420 272 017 444

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1
Eye Damage Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1
Eye Damage Category 1

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Hydrochloric Acid

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P501 Dispose of contents/container in accordance with local/national regulations

P310 Immediately call a POISON CENTER or doctor/physician.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

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Section 3 Composition and Information on Ingredients (Continued)

Hydrochloric Acid CAS # 7647-01-0 EINECS # 231-595-7 Index # 017-002-01-X	<5.0	C;R34-37	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Corrosive. May cause burns to eyes, skin and respiratory tract.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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Section 5 Fire Fighting Measures (Continued)

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Hydrochloric Acid
CAS # 7647-01-0 5 ppm Ceiling; 7 mg/m3 Ceiling

ACGIH

Hydrochloric Acid
CAS # 7647-01-0 2 ppm Ceiling

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Hydrochloric Acid CAS # 7647-01-0	4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

Ireland

Hydrochloric Acid CAS # 7647-01-0	5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

IOELVs

Hydrochloric Acid CAS # 7647-01-0	10 ppm STEL; 15 mg/m3 STEL; 5 ppm TWA; 8 mg/m3 TWA

NIOSH

Hydrochloric Acid CAS # 7647-01-0	50 ppm IDLH

Japan None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.018 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	< 1	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not applicable	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined

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Section 9 Physical and Chemical Properties (Continued)

Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Hydrochloric Acid 0.06 ppm odor threshold value (detectable)		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Hydrochloric Acid CAS # 7647-01-0	Dermal LD50 Rabbit >5010 mg/kg; Inhalation LC50 Rat 1.68 mg/L 1 h; Oral LD50 Rat 238 - 277 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	Contact may cause severe skin burns.
Serious eye damage/eye irritation	Contact may cause serious eye damage.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	Not classified based on available data.

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Section 11 Toxicological Information (Continued)

Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity – single exposure	
	Not classified based on available data.
Specific target organ toxicity – repeated exposure	
	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1	**Ecotoxicity**	
	Fresh Water Species	No information available.
	Microtox	No information available.
	Water Flea	No information available.
	Fresh Water Algae	No information available.
12.2	**Persistence and degradability**	Not determined for the product.
12.3	**Bioaccumulation**	Not determined for the product.
12.4	**Mobility in soil**	Not determined for the product.
12.5	**Results of PBT and vPvB assessment**	
		Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6	**Other Adverse Effects**	No further relevant information available.

Section 13 Disposal Considerations

13.1	**Waste treatment methods**	
	Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2	**Additional information**	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1789	1789	1789	1789	PIN - 1789
14.2	Shipping Name	Hydrochloric acid solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
14.4	Packing Group	II	II	II	II	II
	Special Provisions	A3	None	A3, A6	Not applicable	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	157	Not applicable	157
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313 Hydrochloric Acid is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Hydrochloric Acid is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Hydrochloric Acid is listed.

New Jersey Dept. of Health RTK List

Hydrochloric Acid is listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK Hydrochloric Acid is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 1789

Ingredients on Ingredient Disclosure List

Hydrochloric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes New document

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
R34 Causes burns.
R37 Irritating to respiratory system.
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Skin Corr. 1B - Skin Corrosion Category 1B
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H335 - May cause respiratory irritation.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: A16793-75 Rev. AG
Revised (year/month/day) 2015/04/14

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Wash Buffer II

Part Number A16793

Series Name UniCel DxI

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless to pale yellow; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 15 to 30°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA None established

ACGIH

Sodium Azide
CAS # 26628-22-8 — 0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	≈ 1.01 @20°C
Color	Colorless to pale yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Odorless	**Organic**	Not determined
pH	8.3	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide CAS # 26628-22-8	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

Respiratory/skin sensitization May cause sensitization by skin contact.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
13.2 Additional information	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313	Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration 1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Acetaldehyde is listed. Ethylene Oxide is listed. 1,4-Dioxane is listed. Sodium Azide is listed.
California Proposition 65	Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause cancer. Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause cancer and reproductive harm. 1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. **WARNING**: This product contains a chemical known to the State of California to cause cancer.

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Section 15 Regulatory Information (Continued)

Massachusetts MSL

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi

Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Oxide
1,4-Dioxane
Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes

Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association

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Section 16 Other Information (Continued)

ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%

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BECKMAN COULTER
Wash Solution

SAFETY DATA SHEET

Document ID: OSR0001-75 Version 07
Revision Date (year/month/day) 2018/06/22
Last Revision Date (year/month/day) 2015/03/20

Section 1 of the Substance/mixture and of the Company/undertaking

1.1 Product

Product Name Wash Solution

Part Number ODR2000, OSR0001

1.2 Relevant uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards

2.1 of substance or mixture

Product Description In vitro diagnostic reagent.

Pale Straw; Clear; Liquid; Mild odor

according to EC 1272/2008 (CLP/GHS)

Skin Corrosion Category 1

Eye Damage Category 1

according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Corrosion Category 1

Eye Damage Category 1

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Wash Solution

SAFETY DATA SHEET

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Last Revision Date (year/month/day) 2015/03/20

Section 2 Hazards (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Hydroxide

Sulfonic acids, C14-17-sec-alkane, sodium salts

Genapol X080

Pictogram

Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.

Precautionary Statements

P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard of Pure Ingredients		
Chemical Name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
Sulfonic acids, C14-17-sec-alkane, sodium salts CAS # 97489-15-1 EINECS # 307-055-2 Index # Not available	1 - 5	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	

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Section 3 Composition and Information on Ingredients (Continued)

Sodium Hydroxide CAS # 1310-73-2 EINECS # 215-185-5 Index # 011-002-00-6	1 - 2	Eye Dam. 1, H318 Skin Corr. 1A, H314	Eye Dam. 1, H318 Skin Corr. 1A, H314	
Genapol X080 CAS # 78330-21-9 EINECS # Not available Index # Not available	1 - 2	Acute Tox. Oral 4, H302 Aquatic Longterm 3, H412 Eye Dam. 1, H318	Acute Tox. Oral 4, H302 Aquatic Longterm 3, H412 Eye Dam. 1, H318	

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First Aid Measures

4.1 Description of aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin respiration by trained personnel and obtain medical attention immediately.

Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. Obtain medical advice/attention.

Skin Contact

In case of skin contact, rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Obtain medical advice/attention.

Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Corrosive. May cause burns to eyes, skin and respiratory tract.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing Media

In case of use carbon dioxide (CO_2), dry chemical, water spray or foam.

For large use extinguishing media suitable for surrounding

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing hazards are expected from this product (an aqueous solution).

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Wash Solution

SAFETY DATA SHEET

Document ID: OSR0001-75 Version 07
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Last Revision Date (year/month/day) 2015/03/20

Section 5 Fire Fighting Measures (Continued)

5.3 Advice for

Protective Equipment Self-contained breathing apparatus is recommended for in all chemical situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and tightly sealed eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.
Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non- absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 end uses No further relevant information available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Sodium Hydroxide
CAS # 1310-73-2 2 mg/m3 TWA

ACGIH

Sodium Hydroxide
CAS # 1310-73-2 2 mg/m3 Ceiling

DFG MAK None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Ireland

Sodium Hydroxide CAS # 1310-73-2	2 mg/m3 STEL

IOELVs None established

NIOSH

Sodium Hydroxide CAS # 1310-73-2	10 mg/m3 IDLH

Japan None established

Sweden (AFS 2015:7 and amendments)

Sodium Hydroxide CAS # 1310-73-2	1 mg/m3 LLV; 2 mg/m3 Binding STLV

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.

Respiratory Protection Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Gravity (Water=1.0)**	≈ 1 @20°C
Color	Pale Straw	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Mild odor	**Organic**	Not determined
pH	13.1	**Partition n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Product is not
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa

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Section 9 Physical and Chemical Properties (Continued)

Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Hydroxide
CAS # 1310-73-2 Dermal LD50 Rabbit 1350 mg/kg

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Acute Toxicity Not based on available data.

Skin Corrosion/Irritation Contact may cause severe skin burns.

Serious eye damage/eye irritation Contact may cause serious eye damage.

Respiratory/skin sensitization Not based on available data.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not based on available data.

Reproductive Toxicity Not based on available data.

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Section 11 Toxicological Information (Continued)

target organ toxicity – single exposure

Not based on available data.

target organ toxicity – repeated exposure

Not based on available data.

Aspiration hazard Not based on available data.

Other Information No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Hydroxide
CAS # 1310-73-2 — 96 h LC50 Oncorhynchus mykiss: 45.4 mg/L [static]

Microtox No information available.

Water Flea No information available.

Fresh Water Algae No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional information Suggested European waste catalogue 18 01 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

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Section 14 Transport Information

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	1824	1824	1824	1824	PIN - 1824
14.2	Shipping Name	Sodium hydroxide solution				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Code	Not applicable	Not applicable	Not applicable	C5	Not applicable
14.4	Packing Group	III	III	III	III	III
	Special Provisions	A803	223	N34	None	None
	Additional information					
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5	Environmental Hazards					
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for user

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation for the substance or mixture

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 1310-73-2 Sodium Hydroxide

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

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Section 15 Regulatory Information (Continued)

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 1310-73-2 Sodium Hydroxide
CAS # 7757-82-6 Sodium Sulfate

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 1310-73-2 Sodium Hydroxide

Pennsylvania Right To Know (RTK) List

CAS # 1310-73-2 Sodium Hydroxide
CAS # 7757-82-6 Sodium Sulfate

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for Carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Physical Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Updated the storage temperature. Removed the of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Updated section 4 - 8, 11, 15.	
Document version and issue/revision date		

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Section 16 Other Information (Continued)

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Description of hazard Class and hazard statements from Section 3

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 3 - Aquatic Hazard Long term, Category 3
Skin Corr. 1A - Skin Corrosion Category 1A
Skin Irrit. 2 - Skin Irritation Category 2
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H412 - Harmful to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2015 Reviewed on 05/14/2015

*
1 Identification

· **Product identifier**

· **Trade name: D-10 Wash/Diluent Solution**

· **Catalog or product number:** 220-0112
· **Application of the substance / the mixture** In-vitro laboratory reagent or component

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000

· **Information department:**
Technical services, customer support
TechsupportUSSD@bio-rad.com
· **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Composition/information on ingredients

· **Chemical characterization: Substances**
· **CAS No. Description:**
7732-18-5 water
· **Identification number(s):**
· **EC number:** 231-791-2
· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:** Void
· **Additional information** For the wording of the listed risk phrases refer to section 15.

*
3 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Classification system**
· **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0

*
4 First-aid measures

· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2015 Reviewed on 05/14/2015

Trade name: D-10 Wash/Diluent Solution

(Contd. of page 1)

· **After skin contact** Generally the product does not irritate the skin.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing** Induce vomiting and call for medical help.

5 Fire-fighting measures

· **Suitable extinguishing agents**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Protective equipment:** No special measures required.

*

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Dilute with plenty of water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

*

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.
· **Storage**
· **Requirements to be met by storerooms and receptacles:** According to product specification
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s)** No further relevant information available.

*

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Components with limit values that require monitoring at the workplace:**	
26628-22-8 sodium azide	
REL (United States)	Short-term value: C 0.3** mg/m³, C 0.1* ppm *as HN3 vapor; **as NaN3; Skin
TLV (United States)	Short-term value: C 0.29** mg/m³, C 0.11* ppm *as HN3 vapor **as NaN3

· **Additional information:** The lists that were valid during the creation were used as basis.
· **Personal protective equipment**
· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.

(Contd. on page 3)

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Trade name: D-10 Wash/Diluent Solution

(Contd. of page 2)

· **Breathing equipment:** Not required.
· **Protection of hands:** Protective gloves.
· **Material of gloves** Synthetic gloves
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

*

9 Physical and chemical properties

· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Colorless
· **Odor:**	Odorless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	0 °C
Boiling point/Boiling range:	100 °C
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	
Decomposition temperature:	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 20 °C:**	23 hPa
· **Density at 20 °C:**	1.00005 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	0.0 %
Water:	100.0 %

(Contd. on page 4)

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Trade name: D-10 Wash/Diluent Solution

(Contd. of page 3)

· **Other information** No further relevant information available.

*
10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Incompatible materials:**
This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
· **Hazardous decomposition products:** No dangerous decomposition products known

*
11 Toxicological information

· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritant effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs:** Not applicable.

*
12 Ecological information

· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2015 Reviewed on 05/14/2015

Trade name: D-10 Wash/Diluent Solution

(Contd. of page 4)

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	-

*
15 Regulatory information

· **SARA (Superfund Amendents and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
26628-22-8	sodium azide

· **Section 313 (40CFR372.65):**	
26628-22-8	sodium azide

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

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Trade name: D-10 Wash/Diluent Solution

(Contd. of page 5)

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.
· **Contact:**
Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000
· **Date of preparation / last revision** 06/03/2015 / -
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
· *** Data compared to the previous version altered.**

Safety Data Sheet
Effective Date: January 2021
Supersedes Date: September, 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifier

Product Name	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Product Code	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Relevant identified use(s)	Laboratory use

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US: techsupport@cepheid.com
Telephone (General)	1 (888) 838-3222 - US Option 2
Telephone (General)	1 (408) 541-4191 - Outside of the US
Supplier	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden www.cepheidinternational.com EU: support@cepheideurope.com
Telephone (General)	+33 563 825 319
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
Telephone (Australia)	1800 107 884

1.4 Emergency Telephone Number

Manufacturer	1 (800) 535-5053 - INFOTRAC - 24 hr Emergency
Manufacturer	1 (352) 323-3500 - Outside of the US

Section 2: Hazards Identification

EU/EEC
According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the Substance or Mixture

CLP

The following SDS is for the final finished mixture product only as used in the laboratory. The product contains beads and reagents in the cartridge or in off-board containers. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

CLP

Hazard Statements No label element(s) required

2.3 Other Hazards

CLP

According to Regulation (EC) No. 1272/2008 (CLP) this material is not considered hazardous.

UN GHS (Labeling Content Used on Products)
According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2.1 Classification of the Substance or Mixture

UN GHS

Acute Toxicity Oral 5
Skin Mild Irritation 3
Eye Mild Irritation 2B

2.2 Label Elements

UN GHS

WARNING

Hazard statements

Harmful if swallowed
May be harmful in contact with skin
Causes eye irritation

Precautionary statements

Prevention Wash hands thoroughly after handling.

Response If skin irritation occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Call a POISON CENTER or doctor/physician if you feel unwell.

2.3 Other Hazards

UN GHS — According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous.

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the Substance or Mixture

OSHA HCS 2012 — Eye Mild Irritation 2B

2.2 Label Elements

OSHA HCS 2012

Hazard statements
Harmful if swallowed
May be harmful in contact with skin
Causes eye irritation

Precautionary statements

Prevention — Wash hands thoroughly after handling.

Response — IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

2.3 Other Hazards

OSHA HCS 2012 — Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is not considered hazardous.

Canada
According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS — Not classified

2.2 Label Elements

WHMIS — No label element(s) required.

2.3 Other Hazards

WHMIS — In Canada, the product mentioned above is not considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).

2.4 Other Information

All other reagents, beads, and other constituents are at concentrations less than 1% in the mixture or not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

Section 3: Composition/Information on Ingredients

3.1 Substances

Material does not meet the criteria of a substance.

3.2 Mixtures

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Guanidine Thiocyanate	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**EU CLP:** Acute Tox. 5, H302, H313, H320 **UN GHS:** Acute Tox. 5 (Orl); Skin Irrit. 3; Eye Irrit. 2B **OSHA HCS 2012:** Acute Tox. 5 (Orl); Eye Irrit. 2B	NDA

Section 4: First Aid Measures

4.1 Description of First Aid Measures

Inhalation First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move victim to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing.

Skin First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. For minor skin contact, avoid spreading material on unaffected skin. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Remove and isolate contaminated clothing.

Eye First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. If swallowed, rinse mouth with water (only if the person is conscious) Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Obtain medical attention immediately if ingested.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Refer to Section 11 - Toxicological Information.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	LARGE FIRES: Dry chemical, CO_2, alcohol-resistant foam or water spray. SMALL FIRES: Dry chemical, CO_2 or water spray.
Unsuitable Extinguishing Media	No data available

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	Plastic cartridge containing reagents may emit toxic vapors of carbon oxides, sulfur oxides, nitrogen oxides.
Hazardous Combustion Products	No data available

5.3 Advice for Firefighters

Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.
Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.
Wear positive pressure self-contained breathing apparatus (SCBA).
SMALL FIRES: Move containers from fire area if you can do it without risk.

Section 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions	In the event a cartridge is broken these personal precautions are applicable. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate enclosed areas.
Emergency Procedures	No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

6.3 Methods and Material for Containment and Cleaning Up

Containment/ Clean-up Measures	For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.

6.4 Reference to other sections

Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7: Handling and Storage

7.1 Precautions for safe handling

Handling — No special handling necessary. If cartridge is broken avoid contact with spilled reagents. Avoid contact with skin and eyes.

7.2 Conditions for safe storage, including any incompatibilities

Storage — Store according to product labeling. Keep away from incompatible materials. Store locked up. Keep container/package tightly closed in a cool, well-ventilated place.

7.3 Specific end use(s)

Refer to Section 1.2 - Relevant identified uses.

Section 8: Exposure Controls/Personal Protection

8.1 Control parameters

	Exposure Limits/Guidelines			
	Result	**ACGIH**	**NIOSH**	**OSHA**
Guanidinium thiocyanate	TWA	Not established	Not established	Not established

8.2 Exposure controls

Engineering Measures/Controls — Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory — Respiratory equipment is not expected to be necessary if material is used under ordinary conditions and as recommended. Otherwise, follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face — Wear chemical splash safety goggles.

Skin/Body — Wear protective clothing

Environmental Exposure Controls — Follow best practice for site management and disposal of waste.

Key to abbreviations
OSHA = Occupational Safety and Health Administration
TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Colorless
Odor	Odorless	Odor Threshold	Data lacking
General Properties			
Boiling Point	212 °F(100 °C)	Melting Point/Freezing Point	32 °F(0 °C)
Decomposition Temperature	Data lacking	pH	3.3 to 8.8
Specific Gravity/Relative Density	= 1 Water=1	Water Solubility	Soluble 100 %
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Minimal	Vapor Density	Data lacking
Evaporation Rate	Minimal		
Flammability			
Flash Point	Data lacking	UEL	Data lacking
LEL	Data lacking	Autoignition	Data lacking
Flammability (solid, gas)	Data lacking		
Environmental			
Octanol/Water Partition Coefficient	Data lacking		

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

Incompatible materials. Burning plastic cartridge containing reagents may liberate toxic byproducts

10.5 Incompatible materials

Acids.

10.6 Hazardous decomposition products

Burning plastic cartridge containing reagents may liberate toxic byproducts.

Section 11: Toxicological Information

11.1 Information on toxicological effects

Components		
Guanidinium thiocyanate	593-84-0	**Acute Toxicity:** Intraperitoneal-Mouse LD50 • 593 mg/kg

GHS Properties	Classification
Acute Toxicity	**EU/CLP**•Data lacking **UN GHS**•Acute Toxicity - Oral 5 **OSHA HCS 2012**•Data lacking
Skin Corrosion/Irritation	**EU/CLP**•Data lacking **UN GHS**•Skin Mild Irritation 3 **OSHA HCS 2012**•Data lacking
Serious Eye Damage/Irritation	**EU/CLP**•Data lacking **UN GHS**•Eye Mild Irritation 2B **OSHA HCS 2012**•Eye Mild Irritation 2B
Skin Sensitization	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Respiratory Sensitization	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Carcinogenicity	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Germ Cell Mutagenicity	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Toxicity for Reproduction	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-SE	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking

Potential Health Effects

Inhalation
Acute (Immediate) May cause irritation.
Chronic (Delayed) No data available

Skin
Acute (Immediate) Causes mild skin irritation.
Chronic (Delayed) No data available

Eye
Acute (Immediate) Causes eye irritation.
Chronic (Delayed) No data available

Ingestion
Acute (Immediate) May be harmful if swallowed.
Chronic (Delayed) No data available

Key to abbreviations
LD = Lethal Dose

Section 12: Ecological Information

12.1 Toxicity

LC50 (guppy): 89.1 mg/l @ 96 h

12.2 Persistence and degradability

Material data lacking.

12.3 Bioaccumulative potential

Material data lacking.

12.4 Mobility in Soil

Material data lacking.

12.5 Results of PBT and vPvB assessment

No PBT and vPvB assessment has been conducted.

12.6 Other adverse effects

No studies have been found.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Product waste	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
Packaging waste	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13.2 Other Information

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional diposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO (World Health Organization) medical waste handling and disposal guidelines.

Section 14: Transport Information

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Transport Hazard Class(es)	14.4 Packing Group	14.5 Environmental Hazards
DOT	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable
TDG	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable
IMO/IMDG	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable
IATA/ICAO	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable

14.6 Special Precautions for User

None specified.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Not relevant.

Section 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SARA Hazard Classifications Acute

		Inventory				
Component	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidinium thiocyanate	593-84-0	Yes	No	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances
- Guanidinium thiocyanate — 593-84-0 — Not Listed

Canada - WHMIS - Ingredient Disclosure List
- Guanidinium thiocyanate — 593-84-0 — Not Listed

Environment

Canada - CEPA - Priority Substances List
- Guanidinium thiocyanate — 593-84-0 — Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - OSHA - Specifically Regulated Chemicals
- Guanidinium thiocyanate — 593-84-0 — Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting
- Guanidinium thiocyanate — 593-84-0 — Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing
- Guanidinium thiocyanate — 593-84-0 — Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
•Guanidinium thiocyanate	593-84-0	*Not Listed*
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Guanidinium thiocyanate	593-84-0	Not Listed

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16: Other Information

Relevant Phrases (code & full text)

H302 - Harmful if swallowed
H313 - May be harmful in contact with skin
H320 - Causes eye irritation

Disclaimer/ Statement of Liability

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections, and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

Key to abbreviations
NDA = No data available

Lembar Data Keselamatan
Tanggal Efektif: Januari 2021
Menggantikan Tanggal: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Bagian 1: Identifikasi Zat/Campuran dan Perusahaan/Usaha

1.1 Pengidentifikasi Produk

Nama Produk	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Kode Produk	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Penggunaan Teridentifikasi yang Relevan atas Zat atau Campuran dan Penggunaan yang Tidak Dianjurkan

Penggunaan teridentifikasi yang relevan	Penggunaan Laboratorium

1.3 Detail Pemasok Lembar Data Keselamatan

Produsen		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Amerika Serikat www.cepheid.com AS: techsupport@cepheid.com
	Telepon (Umum)	1 (888) 838-3222 - AS Pilihan 2
	Telepon (Umum)	1 (408) 541-4191 - Di Luar AS
Pemasok		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Swedia www.cepheidinternational.com UE: support@cepheideurope.com
	Telepon (Umum)	+33 563 825 319
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: techsupportANZ@cepheid.com
	Telepon (Australia)	1800 107 884

1.4 Nomor Telepon Darurat

Produsen	1 (800) 535-5053 - INFOTRAC - Darurat 24 jam
Produsen	1 (352) 323-3500 - Di Luar AS

Bagian 2: Identifikasi Bahaya

UE/EEC

Sesuai dengan: Peraturan (EC) No 1272/2008 (CLP)/REACH 1907/2006 [diubah dengan 453/2010]

2.1 Klasifikasi Zat atau Campuran

CLP

LDK yang berikut ini untuk produk campuran jadi akhir saja sebagaimana digunakan di laboratorium. Produk berisi manik dan reagensia dalam kartrid atau dalam wadah di luar sistem. Pengecualian untuk pengungkapan beberapa informasi komponen menurut Artikel CLP 1(5)(d) dan 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Tidak diklasifikasikan

2.2 Elemen Label

CLP

Pernyataan Bahaya Tidak diperlukan elemen label.

2.3 Bahaya Lain

CLP

Sesuai dengan Peraturan (EC) No. 1272/2008 (CLP) bahan ini tidak dianggap berbahaya.

GHS PBB (Pelabelan Kandungan Produk)

Sesuai dengan: Sistem Harmonisasi Global Klasifikasi dan Pelabelan pada Bahan Kimia (GHS) PBB

2.1 Klasifikasi Zat atau Campuran

GHS PBB

Toksisitas Akut Oral 5
Iritasi Kulit Ringan 3
Iritasi Mata Ringan 2B

2.2 Elemen Label

GHS PBB

PERINGATAN

Pernyataan Bahaya

Berbahaya jika tertelan
Dapat berbahaya jika terkena kulit
Menyebabkan iritasi mata

Pernyataan Kehati-hatian

Pencegahan Cuci tangan dengan saksama setelah melakukan penanganan.

Respons Jika terjadi iritasi kulit: Dapatkan saran/bantuan medis.
JIKA TERKENA MATA: Bilas dengan hati-hati menggunakan air selama beberapa menit. Lepaskan lensa kontak, jika ada dan mudah dilakukan. Lanjutkan membilas.
Jika iritasi mata berlanjut: Dapatkan saran/bantuan medis.
Hubungi SENTRA INFORMASI KERACUNAN NASIONAL atau dokter jika Anda merasa kurang sehat.

2.3 Bahaya Lain

GHS PBB Sesuai dengan Sistem Harmonisasi Global Klasifikasi dan Pelabelan (GHS, Globally Harmonized System), produk ini dianggap berbahaya.

Amerika Serikat (AS)
Sesuai dengan: OSHA 29 CFR 1910.1200 HCS

2.1 Klasifikasi Zat atau Campuran

OSHA HCS 2012 Iritasi Mata Ringan 2B

2.2 Elemen Label

OSHA HCS 2012

Pernyataan Bahaya
Berbahaya jika ditelan
Dapat berbahaya jika terkena kulit
Menyebabkan iritasi mata

Pernyataan Kehati-hatian

Pencegahan Cuci tangan dengan saksama setelah melakukan penanganan.

Respons JIKA TERKENA MATA: Bilas dengan hati-hati menggunakan air selama beberapa menit. Lepaskan lensa kontak, jika ada dan mudah dilakukan. Lanjutkan membilas. Jika iritasi mata berlanjut: Dapatkan saran/bantuan medis.

2.3 Bahaya Lain

OSHA HCS 2012 Di bawah Peraturan Amerika Serikat (29 CFR 1910.1200 - Standar Komunikasi Bahaya (Hazard Communication Standard), produk ini tidak dianggap berbahaya.

Kanada
Sesuai dengan: WHMIS

2.1 Klasifikasi Zat atau Campuran

WHMIS Tidak diklasifikasikan

2.2 Elemen Label

WHMIS Tidak diperlukan elemen label.

2.3 Bahaya Lain

WHMIS Di Kanada, produk yang tercantum di atas tidak dianggap berbahaya menurut Sistem Informasi Bahan Berbahaya di Tempat Kerja (WHMIS [Workplace Hazardous Materials Information System]).

2.4 Informasi Lain

Semua reagensia, manik, dan unsur penyusun lain mempunyai konsentrasi kurang dari 1% dalam campuran dan tidak dianggap berbahaya di bawah peraturan komunikasi bahaya AS (29 CFR 1910.1200), petunjuk UE untuk klasifikasi dan pelabelan zat atau campuran atau Sistem Harmonisasi Global untuk klasifikasi dan pelabelan zat atau campuran.

Lembar Data Keselamatan
Tanggal Efektif: Januari 2021
Menggantikan Tanggal: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Bagian 3: Komposisi/Informasi Bahan Penyusun

3.1 Zat

Bahan tidak memenuhi kriteria zat.

3.2 Campuran

Komposisi					
Nama Kimia	**Pengidentifikasi**	**%**	**LD50/LC50**	**Klasifikasi Sesuai dengan Peraturan/Petunjuk**	**Komentar**
Guanidine Tiosianat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10%–20%	593 mg/kg	**CLP UE:** Toks. Akut 5, H302, H313, H320 **GHS PBB:** Toks. Akut 5 (Orl); Irit. Kulit 3; Irit. Mata 2B **OSHA HCS 2012:** Toks. Akut 5 (Orl); Irit. Mata 2B	DTT

Bagian 4: Tindakan Pertolongan Pertama

4.1 Deskripsi Tindakan Pertolongan Pertama

Inhalasi
Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Pindahkan korban ke tempat dengan udara segar. Berikan oksigen jika sulit bernapas. Jangan menggunakan metode pernapasan mulut ke mulut jika korban menghirup zat; berikan pernapasan buatan menggunakan masker saku yang dilengkapi katup satu arah atau alat medis pernapasan lain yang sesuai. Berikan pernapasan buatan jika korban tidak bernapas.

Kulit
Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Untuk kontak kulit sedikit, jangan menyebarkan bahan pada kulit yang tidak terkena. Jika kulit terkena zat, segera bilas kulit dengan air mengalir selama minimal 20 menit. Lepaskan dan pisahkan pakaian yang terkontaminasi.

Mata
Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Jika terkena zat, segera bilas mata dengan air mengalir selama minimal 20 menit. Jika iritasi mata berlanjut: Dapatkan saran/bantuan medis.

Penelanan
Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Jika tertelan, bilas mulut dengan air (hanya jika korban dalam keadaan sadar). JANGAN memaksa untuk memuntahkan. Jangan menggunakan metode pernapasan mulut ke mulut jika korban menelan zat. Segera dapatkan bantuan medis jika tertelan.

4.2 Gejala dan Efek Paling Penting, Baik Akut maupun Tertunda

Lihat Bagian 11 - Informasi Toksikologi.

4.3 Indikasi Diperlukannya Bantuan Medis dan Perawatan Khusus Segera

Catatan untuk Dokter
Semua pengobatan harus didasarkan pada tanda dan gejala penderitaan yang teramati pada pasien. Pertimbangan harus diberikan pada kemungkinan adanya paparan berlebihan terhadap bahan selain produk ini.

Bagian 5: Tindakan Pemadaman Kebakaran

5.1 Media Pemadaman Kebakaran

Media Pemadaman Kebakaran yang Sesuai	KEBAKARAN BESAR: Zat kimia kering, CO2, busa tahan alkohol, semprotan air. KEBAKARAN KECIL: Zat kimia kering, CO2, atau semprotan air.
Media Pemadaman Kebakaran yang Tidak Sesuai	Data tidak tersedia

5.2 Bahaya Khusus yang Timbul dari Zat atau Campuran

Bahaya Kebakaran dan Ledakan yang Tidak Biasa	Kartrid plastik yang berisi reagensia dapat mengeluarkan uap beracun karbon oksida, sulfur oksida, nitrogen oksida.
Produk Pembakaran Berbahaya	Data tidak tersedia

5.3 Saran untuk Petugas Pemadam Kebakaran

Pakaian pelindung petugas pemadam kebakaran struktural memberikan perlindungan terbatas HANYA dalam situasi kebakaran; pakaian tersebut tidak efektif dalam situasi tumpahan saat kontak langsung dengan zat dapat terjadi.
Kenakan pakaian pelindung zat kimia yang direkomendasikan secara spesifik oleh produsen. Pakaian tersebut mungkin menyediakan sedikit perlindungan termal atau tidak sama sekali.
Kenakan alat pernapasan mandiri bertekanan positif (SCBA).
KEBAKARAN KECIL: Pindahkan wadah dari area kebakaran jika Anda dapat melakukannya tanpa risiko.

Bagian 6: Tindakan Penanggulangan jika terjadi Tumpahan dan Kebocoran

6.1 Tindakan Pencegahan Pribadi, Alat Perlindungan Diri, dan Prosedur Darurat

Tindakan Pencegahan Diri	Jika kartrid rusak, tindakan pencegahan diri ini berlaku. Kenakan pakaian pelindung yang sesuai. Jangan berjalan melalui bahan yang tertumpah. Jangan menyentuh wadah yang rusak atau bahan yang tertumpah kecuali mengenakan pakaian pelindung yang sesuai. Beri ventilasi pada area yang tertutup.
Prosedur Tanggap Darurat	Prosedur tanggap darurat dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa sesuai rekomendasi.

6.2 Tindakan Pencegahan Lingkungan

Cegah masuknya zat ke dalam saluran air, saluran pembuangan, ruang bawah tanah, atau ruang tertutup.

6.3 Metode dan Bahan untuk Membendung dan Membersihkan

Tindakan Membendung/ Membersihkan	Untuk tumpahan sedikit, kenakan sarung tangan, dan serap tumpahan dengan handuk kertas. Jangan membuang bahan yang tertumpah ke saluran pembuangan.

6.4 Referensi ke Bagian Lain

Lihat Bagian 8 - Kontrol Paparan/Perlindungan Diri dan Bagian 13 - Pertimbangan Pembuangan/Pemusnahan.

Bagian 7: Penanganan dan Penyimpanan

7.1 Tindakan Pencegahan untuk Penanganan Aman

Penanganan Tidak diperlukan penanganan khusus. Jika kartrid rusak, hindari kontak dengan reagensia yang tertumpah. Hindari kontak dengan kulit dan mata.

7.2 Kondisi untuk Penyimpanan Aman, Termasuk Inkompatibilitas

Penyimpanan Simpan sesuai dengan label produk. Jauhkan dari bahan yang tidak kompatibel. Simpan di tempat terkunci. Simpan wadah/kemasan dalam keadaan tertutup rapat di tempat yang sejuk dan berventilasi baik.

7.3 Penggunaan Akhir Spesifik

Lihat Bagian 1.2 - Penggunaan teridentifikasi yang relevan.

Bagian 8: Kontrol Paparan/Perlindungan Diri

8.1 Parameter Kontrol

	Batas/Pedoman Paparan			
	Hasil	**ACGIH**	**NIOSH**	**OSHA**
Guanidinium tiosianat	TWA	Tidak ditentukan	Tidak ditentukan	Tidak ditentukan

8.2 Kontrol Paparan

Kontrol/Tindakan Teknik Ventilasi umum yang baik harus digunakan. Tingkat ventilasi harus disesuaikan dengan kondisi. Jika relevan, gunakan penutup proses, ventilasi pembuangan lokal, atau kontrol rekayasa lain untuk menjaga tingkat zat yang terbawa udara berada di bawah batas paparan yang disarankan. Jika batas paparan belum ditentukan, jaga tingkat zat yang terbawa udara pada tingkat yang dapat diterima.

Alat Perlindungan Diri

Pernapasan Alat pernapasan dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Sebaliknya, ikuti peraturan respirator OSHA yang ada di dalam 29 CFR 1910.134 atau Standar Eropa EN 149. Gunakan respirator yang disetujui oleh NIOSH/MSHA atau Standar Eropa EN 149 jika batas paparan terlampaui atau gejala dialami.

Mata/Wajah Kenakan kacamata pengaman untuk cipratan zat kimia.

Kulit/Tubuh Kenakan pakaian pelindung

Kontrol Paparan Lingkungan Ikuti praktik terbaik untuk pengelolaan lokasi dan pembuangan limbah.

Penjelasan singkatan
OSHA = Occupational Safety and Health Administration (Administrasi Kesehatan dan Keselamatan Kerja)
TWA = Time-Weighted Averages, rata-rata terbobot waktu didasarkan pada paparan 8 jam/hari, 40 jam/minggu

Bagian 9: Sifat Fisika dan Kimia

9.1 Informasi tentang Sifat Fisika dan Kimia

Deskripsi Bahan			
Bentuk Fisik	Cairan	Warna	Tanpa warna
Bau	Tanpa bau	Ambang Bau	Data tidak cukup
Sifat Umum			
Titik Didih	100 °C (212 °F)	Titik Leleh/Titik Beku	0 °C (32 °F)
Suhu Dekomposisi	Data tidak cukup	pH	3,3 hingga 8,8
Berat Jenis/Densitas Relatif	= 1 Air=1	Kelarutan Air	Larut 100%
Kekentalan	Data tidak cukup	Sifat Eksplosif	Data tidak cukup
Sifat Pengoksidasi:	Data tidak cukup		
Volatilitas			
Tekanan Uap	Minimal	Densitas Uap	Data tidak cukup
Laju Penguapan	Minimal		
Kemudahan Menyala			
Titik Nyala	Data tidak cukup	UEL	Data tidak cukup
LEL	Data tidak cukup	Swasulut	Data tidak cukup
Kemudahan Menyala (padat, gas)	Data tidak cukup		
Lingkungan			
Koefisien Partisi Oktanol/Air	Data tidak cukup		

9.2 Informasi Lain

Tidak tercatat adanya parameter fisika dan kimia tambahan.

Bagian 10: Stabilitas dan Reaktivitas

10.1 Reaktivitas

Tidak ada reaksi berbahaya yang diketahui di bawah kondisi penggunaan normal.

10.2 Stabilitas Kimia

Stabil

10.3 Kemungkinan Reaksi Berbahaya

Polimerisasi berbahaya tidak akan terjadi.

10.4 Kondisi untuk Dihindari

Bahan yang Tidak Kompatibel. Membakar kartrid plastik berisi reagensia dapat melepaskan produk sampingan beracun

10.5 Bahan yang Tidak Kompatibel

Asam.

10.6 Produk dekomposisi berbahaya

Membakar kartrid plastik berisi reagensia dapat melepaskan produk sampingan beracun.

Lembar Data Keselamatan
Tanggal Efektif: Januari 2021
Menggantikan Tanggal: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Bagian 11: Informasi Toksikologi

11.1 Informasi efek toksikologi

Komponen		
Guanidinium tiosianat	593-84-0	**Toksisitas Akut:** Intraperitoneal-Mencit LD50 • 593 mg/kg

Sifat GHS	Klasifikasi
Toksisitas Akut	**UE/CLP**•Data tidak cukup **GHS PBB**•Toksisitas Akut - Oral 5 **OSHA HCS 2012**•Data tidak cukup
Korosi/Iritasi Kulit	**UE/CLP**•Data tidak cukup **GHS PBB**•Iritasi Kulit Ringan 3 **OSHA HCS 2012**•Data tidak cukup
Kerusakan/Iritasi Mata Serius	**UE/CLP**•Data tidak cukup **GHS PBB**•Iritasi Mata Ringan 2B **OSHA HCS 2012**•Iritasi Mata Ringan 2B
Sensitisasi Kulit	**UE/CLP**•Data tidak cukup **GHS PBB**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Sensitisasi Pernapasan	**UE/CLP**•Data tidak cukup **GHS PBB**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Karsinogenisitas	**UE/CLP**•Data tidak cukup **GHS PBB**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Mutagenisitas Sel Nutfah	**UE/CLP**•Data tidak cukup **GHS PBB**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Toksisitas untuk Reproduksi	**UE/CLP**•Data tidak cukup **GHS PBB**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Toksisitas Organ Target Spesifik - Paparan Tunggal (STOT-SE, Specific Target Organ Toxicity - Single Exposure)	**UE/CLP**•Data tidak cukup **GHS PBB**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup

Potensi Efek Kesehatan

Inhalasi
Akut (Segera) Dapat menyebabkan iritasi.
Kronis (Tertunda) Data tidak tersedia

Kulit
Akut (Segera) Menyebabkan iritasi kulit ringan.
Kronis (Tertunda) Data tidak tersedia

Mata
Akut (Segera) Menyebabkan iritasi mata.
Kronis (Tertunda) Data tidak tersedia

Penelanan
Akut (Segera) Dapat berbahaya jika ditelan.
Kronis (Tertunda) Data tidak tersedia

Penjelasan singkatan
LD = Lethal Dose (Dosis Mematikan)

Bagian 12: Informasi Ekologis

12.1 Toksisitas

LC50 (ikan gupi): 89,1 mg/l pada 96 jam

12.2 Persistensi dan Keteruraian

Data bahan tidak cukup.

12.3 Potensi Bioakumulatif

Data bahan tidak cukup.

12.4 Mobilitas dalam Tanah

Data bahan tidak cukup.

12.5 Hasil pengkajian PBT dan vPvB

Belum dilakukan pengkajian PBT dan vPvB.

12.6 Efek Merugikan yang Lain

Belum ada penelitian.

Bagian 13: Pertimbangan Pembuangan/Pemusnahan

13.1 Metode Penanganan Limbah

Limbah produk	Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.
Limbah kemasan	Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.

13.2 Informasi Lain

Spesimen biologis, alat transfer, dan kartrid bekas pakai harus dianggap sebagai mampu menularkan agen penyebab infeksi, yang membutuhkan kewaspadaan standar. Ikuti prosedur limbah lingkungan institusi Anda untuk pembuangan dengan benar kartrid bekas dan reagensia tidak terpakai. Berbagai bahan ini dapat menunjukkan karakteristik limbah kimia berbahaya yang membutuhkan prosedur pembuangan spesifik nasional atau regional. Jika peraturan negara atau regional tidak menyediakan arahan yang jelas mengenai pembuangan dengan benar, spesimen biologis dan kartrid bekas harus dibuang sesuai pedoman penanganan dan pembuangan limbah medis dari Organisasi Kesehatan Dunia (WHO, World Health Organization).

Bagian 14: Informasi Pengangkutan

	14.1 Nomor PBB	14.2 Nama Pengapalan yang Sesuai Berdasarkan PBB	14.3 Klasifikasi Bahaya Pengangkutan	14.4 Kelompok Pengemasan	14.5 Bahaya Lingkungan
DOT	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku
TDG	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku
IMO/IMDG	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku
IATA/ICAO	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku

14.6 Tindakan Pencegahan Khusus untuk Pengguna

Tidak ditentukan.

14.7 Pengangkutan dalam Jumlah Besar menurut Lampiran II dari MARPOL 73/78 dan Pedoman IBC

Tidak relevan.

Bagian 15: Informasi Peraturan

15.1 Peraturan/Undang-Undang Keselamatan, Kesehatan, dan Lingkungan yang Spesifik untuk Zat dan Campuran

Klasifikasi Bahaya SARA Akut

Inventaris						
Komponen	**CAS**	**Kanada DSL**	**Kanada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Guanidinium tiosianat	593-84-0	Ya	Tidak	Ya	Tidak	Ya

Kanada

Tenaga Kerja

Kanada - WHMIS - Klasifikasi Zat

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Kanada - WHMIS - Daftar Pengungkapan Kandungan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Lingkungan

Kanada - CEPA - Daftar Zat Prioritas

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Amerika Serikat

Tenaga Kerja

A.S. - OSHA - Manajemen Keamanan Proses - Zat Kimia Sangat Berbahaya

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - OSHA - Zat Kimia Teregulasi Secara Spesifik

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Lingkungan

A.S. - Undang-Undang Udara Bersih (CAA, Clean Air Act) - 1990 Polutan Udara Berbahaya

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Zat Berbahaya dan Kuantitas yang Dilaporkan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Radionuklida dan Kuantitas yang Dilaporkan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 302 Zat yang Amat Sangat Berbahaya EPCRA RQs

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 302 Zat yang Amat Sangat Berbahaya TPQs

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 313 - Pelaporan Emisi

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 313 - Daftar Zat Kimia PBT

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Amerika Serikat - California

Lingkungan

A.S. - California - Proposisi 65 - Daftar Karsinogen		
•Guanidinium tiosianat	593-84-0	Tidak Tercantum
A.S. - California - Proposisi 65 - Toksisitas Perkembangan		
•Guanidinium tiosianat	593-84-0	*Tidak Tercantum*
A.S. - California - Proposisi 65 - Tingkat Dosis Maksimum yang Diizinkan (MADL, Maximum Allowable Dose Levels)		
•Guanidinium tiosianat	593-84-0	Tidak Tercantum
A.S. - California - Proposisi 65 - Tingkat Risiko yang Tidak Signifikan (NSRL, No Significant Risk Levels)		
•Guanidinium tiosianat	593-84-0	Tidak Tercantum
A.S. - California - Proposisi 65 - Toksisitas Reproduktif - Perempuan		
•Guanidinium tiosianat	593-84-0	Tidak Tercantum
A.S. - California - Proposisi 65 - Toksisitas Reproduktif - Laki-laki		
•Guanidinium tiosianat	593-84-0	Tidak Tercantum

15.2 Pengkajian Keamanan Zat Kimia

Belum dilakukan Pengkajian Keamanan Zat Kimia.

Bagian 16: Informasi Lain

Frasa yang Relevan (kode dan teks lengkap)

H302 - Berbahaya jika ditelan
H313 - Dapat berbahaya jika terkena kulit
H320 - Menyebabkan iritasi mata

Penafian/ Pernyataan Liabilitas

Informasi di atas didasarkan pada data yang tersedia bagi kami dan diyakini kebenarannya. Karena informasi tersebut dapat diterapkan dalam kondisi di luar kendali kami dan dengan cara yang asing bagi kami, kami tidak bertanggung jawab atas hasil penggunaannya dan semua orang yang menerimanya harus menentukan sendiri dampak, sifat, perlindungan, dan pembuangan yang sesuai dengan kondisi khususnya. Tidak ada pernyataan, jaminan, atau garansi, secara tegas atau tersirat (termasuk jaminan akan kesesuaian atau kelayakan diperdagangkan untuk tujuan khusus), yang dibuat berhubungan dengan bahan, akurasi informasi ini, hasil yang akan didapatkan dari penggunaannya, atau bahaya yang terkait dengan penggunaan bahan. Kehati-hatian harus digunakan dalam penanganan dan penggunaan bahan. Informasi di atas diberikan dengan iktikad baik dan dengan keyakinan bahwa itu akurat. Pada tanggal penerbitan, kami menyediakan semua informasi yang relevan dengan penanganan bahan yang diketahui sebelumnya. Namun, jika ada kejadian merugikan yang berhubungan dengan produk ini, Lembar Data Keselamatan bukan, dan tidak ditujukan untuk menggantikan konsultasi dengan personel terlatih yang sesuai.

Penjelasan singkatan
DTT = Data tidak tersedia

Sikkerhedsdatablad
Ikrafttrædelsesdato: Januar 2021
Erstatter datoen: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Punkt 1: Identifikation af stosssffet/blandingen og af selskabet/virksomheden

1.1 Produktidentifikator

Handelsnavn **Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**

Artikelnummer 900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Anbefalede anvendelser for stoffet eller blandingen samt anvendelser, der frarådes

Anbefalede anvendelser Laboratoriebrug

1.3 Nærmere oplysninger om leverandøren af sikkerhedsdatabladet

Producent
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA
www.cepheid.com
USA: techsupport@cepheid.com

Telefon (generelt) 1 (888) 838-3222 - USA - Tast 2

Telefon (generelt) 1 (408) 541-4191 - Uden for USA

Leverandør
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sverige
www.cepheidinternational.com
EU: support@cepheideurope.com

Telefon (generelt) +33 563 825 319

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
Australien
www.cepheidinternational.com
ANZ: TechSupportANZ@cepheid.com

Telefon (Australien) 1800 107 884

1.4 Nødtelefon

Producent 1 (800) 535-5053 - INFOTRAC - Døgnåben nødtelefon

Producent 1 (352) 323-3500 - Uden for USA

Sikkerhedsdatablad
Ikrafttrædelsesdato: Januar 2021
Erstatter datoen: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Punkt 2: Fareidentifikation

EU/EØF

I henhold til: Forordning (EF) nr. 1272/2008 (CLP)/REACH 1907/2006 [ændret ved 453/2010]

2.1 Klassificering af stoffet eller blandingen

CLP-forordning

Dette sikkerhedsdatablad (SDS) gælder for det blandede slutprodukt kun som anvendt på laboratoriet. Produktet indeholder perler og reagenser i kassetten eller i separate beholdere. Undtagelser vedrørende offentliggørelse af oplysninger om visse komponenter skal ske iht. CLP paragraf 1(5)(d) og 29 CFR 1910.1200(g)(2)(i)(C)(1)og(2).
Ikke klassificeret

2.2 Mærkningselementer

CLP

H-sætninger Ingen mærkningselementer påkrævet

2.3 Andre farer

CLP-forordning

I henhold til forordning (EF) nr. 1272/2008 (CLP) anses materialet ikke som værende farligt.

UN GHS (Mærkning indhold bruges på produkter)

I henhold til: FNs globale harmoniserede system til klassificering og mærkning af kemikalier (GHS)

2.1 Klassificering af stoffet eller blandingen

UN GHS

Akut toksicitet - oral 5
Mild hudirritation 3
Mild øjenirritation 2B

2.2 Mærkningselementer

UN GHS

ADVARSEL

Faresætninger
Farlig ved indtagelse
Kan være skadeligt ved kontakt med huden
Forårsager øjenirritation

Signalord

Forebyggelse Vask hænderne grundigt efter håndtering.

Reaktion
Ved hudirritation: Søg lægehjælp.
VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.
Ved vedvarende øjenirritation: Søg lægehjælp.
I tilfælde af ubehag ring til en GIFTINFORMATION eller en læge.

2.3 Andre farer

UN GHS I henhold til det globale harmoniserede system til klassificering og mærkning af kemikalier (GHS) anses dette produkt som farligt.

USA
I henhold til: OSHA 29 CFR 1910.1200 HCS

2.1 Klassificering af stoffet eller blandingen

OSHA HCS 2012 Mild øjenirritation 2B

2.2 Mærkningselementer

OSHA HCS 2012

Faresætninger Farlig ved indtagelse
Kan være skadeligt ved kontakt med huden
Forårsager øjenirritation

Signalord

Forebyggelse Vask hænderne grundigt efter håndtering.

Reaktion VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.
Ved vedvarende øjenirritation: Søg lægehjælp.

2.3 Andre farer

OSHA HCS 2012 I henhold til Forordning (USA) - Hazard Communication Standard 29 CFR 1910.1200 anses dette produkt ikke for at være farligt.

Canada
I henhold til: WHMIS

2.1 Klassificering af stoffet eller blandingen

WHMIS Ikke klassificeret

2.2 Mærkningselementer

WHMIS Ingen mærkningselementer påkrævet.

2.3 Andre farer

WHMIS I Canada anses ovenstående produkt ikke for at være farligt iht. Workplace Hazardous Materials Information System (WHMIS).

2.4 Andre oplysninger

Alle andre reagenser, perler og andre indholdsstoffer forekommer i koncentrationer på mindre end 1 % i blandingen, eller anses ikke for farlige iht. amerikanske forordninger vedrørende fare (29 CFR 1910.1200), EU-direktiver til klassifikation og mærkning af stoffer eller blandinger, eller Global Harmonization System til klassifikation og mærkning af stoffer eller blandinger.

Punkt 3: Sammensætning af/oplysning om indholdsstoffer

3.1 Stoffer

Materialet opfylder ikke kriterierne for et stof.

3.2 Blandinger

Sammensætning					
Kemisk navn	**Identifikatorer**	**%**	**LD50/LC50**	**Klassificeringer iht. forordning/direktiv**	**Bemærkninger**
Guanidinthiocyanat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10-20 %	593 mg/kg	**EU CLP:** Akut toks. 5, H302, H313, H320 **UN GHS:** Akut toks. 5 (oral), hudirrit. 3, Øjenirrit. 2B **OSHA HCS 2012:** Akut toks. 5 (oral), Øjenirrit. 2B	NDA

Punkt 4: Førstehjælpsforanstaltninger

4.1 Beskrivelse af førstehjælpsforanstaltninger

Indånding Førstehjælp forventes ikke at være nødvendigt, hvis materialet anvendes under normale forhold og som anbefalet. Flyt personen til et sted med frisk luft. Brug iltmaske ved vejrtrækningsbesvær. Brug ikke mund-til-mund metoden, hvis den tilskadekomne indåndede stoffet. Giv kunstigt åndedræt ved hjælp af en lommemaske, der er udstyret med en envejsventil eller andet korrekt respirationsudstyr. Giv kunstigt åndedræt, hvis den tilskadekomne ikke trækker vejret.

Hud Førstehjælp forventes ikke at være nødvendigt, hvis materialet anvendes under normale forhold og som anbefalet. Ved mindre hudkontakt undgå at sprede materialet til den upåvirkede hud. Ved kontakt med stoffet, skyl øjeblikkeligt huden med rigelige mængder vand i mindst 20 minutter. Forurenet tøj og sko tages af.

Øjne Førstehjælp forventes ikke at være nødvendigt, hvis materialet anvendes under normale forhold og som anbefalet. Ved kontakt med stoffet, skyl øjnene med rigelige mængder vand i mindst 20 minutter. Ved vedvarende øjenirritation: Søg lægehjælp.

Indtagelse Førstehjælp forventes ikke at være nødvendigt, hvis materialet anvendes under normale forhold og som anbefalet. Ved indtagelse, skyl munden med vand (kun hvis personen er ved bevidsthed). Fremkald IKKE opkastning. Brug ikke mund-til-mund genoplivning, hvis stoffet blev indtaget. Søg omgående lægehjælp ved indtagelse.

4.2 Vigtigste symptomer og virkninger, både akutte og forsinkede

Se punkt 11 - Toksikologiske oplysninger.

4.3 Angivelse af om øjeblikkelig lægehjælp og særlig behandling er nødvendig

Anmærkninger til lægen Der bør behandles symptomatisk. Der bør tages forbehold for, at overeksponering for andre materialer end dette produkt kan have fundet sted.

Punkt 5: Brandbekæmpelse

5.1 Slukningsmidler

Egnede slukningsmidler	STØRRE BRAND: Slukningspulver, CO2, alkoholbestandigt skum eller vandtåge. MINDRE BRANDE: Slukningspulver, CO2 eller vandtåge.
Uegnede slukningsmidler	Ingen data

5.2 Særlige farer i forbindelse med stoffet eller blandingen

Usædvanlige brand- eller eksplosionsfarer	En plastbeholder indeholdende reagenser kan danne de toksiske luftarter karbonoxider, svovloxider, nitrogenoxider.
Farlige forbrændingsprodukter	Ingen data

5.3 Anvisninger for brandslukningspersonale

Beskyttelsesdragter til brandslukningspersonale yder begrænset beskyttelse KUN ved ildebrande. Dragterne er ikke effektive ved spild, hvor direkte kontakt med stoffet kan finde sted.
Benyt særlige kemiske beskyttelsesdragter som anbefalet af producenten. Disse yder muligvis kun ringe eller ingen beskyttelse mod kraftig varme.
Benyt selvforsynet, lufttilført åndedrætsapparatur (SCBA), som skal anvendes i positiv tryktilstand.
MINDRE BRANDE: Flyt beholdere fra brandområdet, hvis dette kan gøres forsvarligt.

Punkt 6: Forholdsregler over for udslip ved uheld

6.1 Personlige sikkerhedsforanstaltninger, personlige værnemidler og nødprocedurer

Personlige sikkerhedsforanstaltninger	Hvis en beholder er brudt, gælder disse personlige sikkerhedsforanstaltninger. Bær passende beskyttelsesdragter. Gå ikke igennem det spildte materiale. Rør ikke ved beskadigede beholdere eller spildt materiale uden at bære passende beskyttelsesdragt. Sørg for tilstrækkelig ventilation.
Tiltag i nødsituationer	Nødberedskab forventes ikke at være nødvendigt, så længe materialet anvendes under normale forhold som anbefalet.

6.2 Miljøbeskyttelsesforanstaltninger

Undgå spredning af spildt materiale til vandveje, kloakker, kælderrum eller lukkede områder.

6.3 Metoder og udstyr til inddæmpning og oprensning

Inddæmning og oprensning	Ved mindre udslip anvendes handsker. Opsaml spildet med papirhåndklæder. Hæld ikke spildt materiale i vasken.

6.4 Henvisning til andre punkter

Se punkt 8 - Eksponeringskontrol/personlige værnemidler og punkt 13 - Forhold vedrørende bortskaffelse.

Punkt 7: Håndtering og opbevaring

7.1 Forholdsregler for sikker håndtering

Håndtering Ingen særlige krav. Hvis beholderen er brudt, skal enhver kontakt med spildt reagens undgås. Undgå kontakt med hud og øjne.

7.2 Betingelser for sikker opbevaring, herunder eventuel uforenelighed

Opbevaring Opbevares som angivet på produktmærkningen. Holdes væk fra uforenelige materialer. Opbevares under lås. Hold beholderen/pakken tæt lukket på et godt ventileret sted.

7.3 Særlige anvendelser

Se punkt 1.2 - Relevante identificerede anvendelser.

Punkt 8: Eksponeringskontrol/personlige værnemidler

8.1 Kontrolparametre

	Grænseværdier/retningslinjer			
	Resultat	**ACGIH**	**NIOSH**	**OSHA**
Guanidiniumthiocyanat	TWA	Ikke fastlagt	Ikke fastlagt	Ikke fastlagt

8.2 Eksponeringskontrol

Egnede foranstaltninger til eksponeringskontrol Sørg for tilstrækkelig ventilation. Omfanget af ventilation skal svare til forholdene. Hvis relevant anvendes afskærmning, udsugning i området eller andre foranstaltninger for at holde luftforurening under de anbefalede eksponeringsgrænser. Hvis der ikke er fastlagt eksponeringsgrænser, skal luftforurening holdes på acceptable niveauer.

Personlige værnemidler

Åndedrætsværn Respirationsudstyr forventes ikke at være nødvendigt, hvis materialet anvendes under normale forhold og som anbefalet. Ellers følges OSHA-bestemmelserne om åndedrætsværn i 29 CFR 1910.134 eller europæisk standard EN 149. Der skal bruges NIOSH/MSHA eller åndedrætsværn i henhold til europæisk standard EN 149, hvis eksponeringsgrænserne overskrides eller der opstår symptomer.

Ansigtbeskyttelse Bær beskyttelsesbriller beregnet til brug med kemiske stoffer.

Hud-/kropsbeskyttelse Bær beskyttelsestøj

Miljøeksponeringskontrol Det skal sikres at lokale regler for udledning overholdes.

Forkortelser:
OSHA = Occupational Safety and Health Administration (det amerikanske arbejdsmiljøtilsyn)
TWA = Time-Weighted Averages (tidsvægtede gennemsnit) baseret på en 8-timers arbejdsdag eller 40-timers arbejdsuge

Punkt 9: Fysisk-kemiske egenskaber

9.1 Oplysninger om grundlæggende fysiske og kemiske egenskaber

Beskrivelse			
Tilstandsform	Flydende	Farve	Farveløs
Lugt	Lugtfri	Lugttærskel	Ingen data
Generelle oplysninger			
Kogepunkt	100 °C	Smeltepunkt/frysepunkt	0 °C
Dekomponeringstemperatur	Ingen data	pH	3,3 til 8,8
Specifik tyngde/relativ tæthed	= 1 Vand=1	Opløselighed i vand	100 % vandopløselig
Viskositet	Ingen data	Eksplosive egenskaber	Ingen data
Oxiderende egenskaber:	Ingen data		
Flygtighed			
Damptryk	Minimalt	Damptæthed	Ingen data
Fordampningshastighed	Minimalt		
Antændelighed			
Flammepunkt	Ingen data	Øvre eksplosionsgrænse	Ingen data
Nedre eksplosionsgrænse	Ingen data	Selvantændelsespunkt	Ingen data
Antændelighed (fast stof, luftart)	Ingen data		
Miljøeksponeringskontrol			
Octanol/vand-fordelingskoefficient	Ingen data		

9.2 Andre oplysninger

Ingen yderligere fysiske og kemiske parametre angivet.

Punkt 10: Stabilitet og reaktivitet

10.1 Reaktivitet

Ingen kendt reaktivitet under normale betingelser.

10.2 Kemisk stabilitet

Stabilt

10.3 Risiko for farlige reaktioner

Farlig polymerisering forekommer ikke.

10.4 Forhold, der skal undgås

Materialer, der skal undgås. Afbrænding af en plastbeholder indeholdende reagenser kan frigive toksiske biprodukter.

10.5 Materialer, der skal undgås

Syrer.

10.6 Farlige nedbrydningsprodukter

Afbrænding af en plastbeholder indeholdende reagenser kan frigive toksiske biprodukter.

Punkt 11: Toksikologiske oplysninger

11.1 Oplysninger om toksikologiske virkninger

Bestanddele		
Guanidiniumthiocyanat	593-84-0	**Akut toksicitet:** Intraperitonealt-mus LD50 • 593 mg/kg

GHS-egenskaber	Klassifikation
Akut toksicitet	**EU/CLP**•Ingen data **UN GHS**•Akut toksicitet - Oral 5 **OSHA HCS 2012**•Ingen data
Hudætsning/-irritation	**EU/CLP**•Ingen data **UN GHS**•Mild hudirritation 3 **OSHA HCS 2012**•Ingen data
Alvorlig øjenskade/-irritation	**EU/CLP**•Ingen data **UN GHS**•Mild øjenirritation 2B **OSHA HCS 2012**•Mild øjenirritation 2B
Hudsensibilisering	**EU/CLP**•Ingen data **UN GHS**•Ingen data **OSHA HCS 2012**•Ingen data
Respiratorisk sensibilisering	**EU/CLP**•Ingen data **UN GHS**•Ingen data **OSHA HCS 2012**•Ingen data
Karcinogenicitet	**EU/CLP**•Ingen data **UN GHS**•Ingen data **OSHA HCS 2012**•Ingen data
Kimcellemutagenicitet	**EU/CLP**•Ingen data **UN GHS**•Ingen data **OSHA HCS 2012**•Ingen data
Reproduktionstoksicitet	**EU/CLP**•Ingen data **UN GHS**•Ingen data **OSHA HCS 2012**•Ingen data
Enkel STOT-eksponering	**EU/CLP**•Ingen data **UN GHS**•Ingen data **OSHA HCS 2012**•Ingen data

Potentielle helbredsmæssige virkninger

Indånding
Akut (omgående) Kan forårsage irritation.
Kronisk (forsinket) Data foreligger ikke

Hud
Akut (omgående) Forårsager mild hudirritation.
Kronisk (forsinket) Data foreligger ikke

Øjne
Akut (omgående) Forårsager øjenirritation.
Kronisk (forsinket) Data foreligger ikke

Indtagelse
Akut (omgående) Kan være farlig ved indtagelse.
Kronisk (forsinket) Data foreligger ikke

Forkortelser:
LD = Lethal Dose (dødelig dosis)

Punkt 12: Miljøoplysninger

12.1 Toksicitet

LC50 (gubbi): 89,1 mg/l ved 96 t

12.2 Persistens og nedbrydelighed

Testdata foreligger ikke.

12.3 Bioakkumuleringspotentiale

Testdata foreligger ikke.

12.4 Mobilitet i jord

Testdata foreligger ikke.

12.5 Resultater af PBT- og vPvB-vurdering

Vurdering er ikke foretaget.

12.6 Andre negative virkninger

Der står ingen yderligere, relevante informationer til rådighed.

Punkt 13: Forhold vedrørende bortskaffelse

13.1 Metoder til affaldsbehandling

Produktaffald	Bortskaffelse af indholdet af og/eller beholder skal ske i overensstemmelse med alle lokale, regionale, nationale og/eller internationale krav.
Emballageaffald	Bortskaffelse af indholdet af og/eller beholder skal ske i overensstemmelse med alle lokale, regionale, nationale og/eller internationale krav.

13.2 Andre oplysninger

Biologiske prøver, overførselsudstyr og brugte beholdere skal behandles som værende i stand til at overføre smitstoffer, der kræver brug af standardforholdsregler. Overhold institutionens procedurer for miljøaffald vedrørende korrekt bortskaffelse af brugte beholdere og ubrugte reagenser. Dette materiale kan udvise egenskaber svarende til kemisk farligt affald, der skal bortskaffes ifølge specifikke nationale eller regionale procedurer. Hvis nationale eller regionale forordninger ikke indeholder klare retningslinjer for korrekt bortskaffelse, skal biologiske prøver og brugte beholdere bortskaffes ifølge retningslinjer fra WHO (World Health Organization) vedrørende håndtering og bortskaffelse af medicinsk affald.

Punkt 14: Transportoplysninger

	14.1 UN-nummer	14.2 UN-forsendelsesbetegnelse (UN Proper Shipping Name)	14.3 Transportfareklasse(r)	14.4 Emballagegruppe	14.5 Miljøfarer
DOT	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke relevant
TDG	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke relevant
IMO/IMDG	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke relevant
IATA/ICAO	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke reguleret	Ikke relevant

14.6 Særlige forsigtighedsregler for brugeren

Ingen angivet.

14.7 Bulktransport i henhold til bilag II i MARPOL 73/78 og IBC-koden

Ikke relevant.

Punkt 15: Oplysninger om regulering

15.1 Særlige bestemmelser/særlig lovgivning for stoffet eller blandingen med hensyn til sikkerhed, sundhed og miljø

SARA fareklassifikation Akut

Oversigt over kemikalier						
Komponent	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidiniumthiocyanat	593-84-0	Ja	Nej	Ja	Nej	Ja

Canada

Arbejdsplads

Canada - WHMIS - Klassifikation af stoffer

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

Canada - WHMIS - Information om indholdsstoffer

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

Miljø

Canada - CEPA - Information om prioriterede stoffer

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

USA

Arbejdsplads

U.S. - OSHA - Processikkerhedsstyring - Meget farlige kemikalier

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - OSHA - Særligt regulerede kemikalier

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

Miljø

U.S. - CAA (Clean Air Act) - 1990 Farlige luftforureningsstoffer

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - CERCLA/SARA - Farlige stoffer og deres rapporterbare mængder

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - CERCLA/SARA - Radionuklider og deres rapporterbare mængder

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - CERCLA/SARA - Paragraf 302 Ekstremt farlige stoffer EPCRA RQ

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - CERCLA/SARA - Paragraf 302 Ekstremt farlige stoffer TPQ

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - CERCLA/SARA - Paragraf 313 - Emissionsrapportering

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

U.S. - CERCLA/SARA - Paragraf 313 - Liste over PBT-kemikalier

• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

USA - Californien

Miljø

USA - Californien - Erklæring 65 - Liste over kræftfremkaldende stoffer		
• Guanidiniumthiocyanat	593-84-0	Ikke oplyst
USA - Californien - Erklæring 65 - Udvikling af toksicitet		
• Guanidiniumthiocyanat	593-84-0	*Ikke oplyst*
USA - Californien - Erklæring 65 - Maksimale tilladte dosisniveauer (MADL)		
• Guanidiniumthiocyanat	593-84-0	Ikke oplyst
USA - Californien - Erklæring 65 - Ingen signifikante risikoniveauer (NSRL)		
• Guanidiniumthiocyanat	593-84-0	Ikke oplyst
USA - Californien - Erklæring 65 - Reproduktionstoksicitet - Kvinder		
• Guanidiniumthiocyanat	593-84-0	Ikke oplyst
USA - Californien - Erklæring 65 - Reproduktionstoksicitet - Mænd		
• Guanidiniumthiocyanat	593-84-0	Ikke oplyst

15.2 Kemikaliesikkerhedsvurdering

Der er ikke udført kemikaliesikkerhedsvurdering.

Punkt 16: Andre oplysninger

Relevante sætninger (nummer og hel tekst)

H302 – Farlig ved indtagelse
H313 – Kan være skadeligt ved kontakt med huden
H320 – Forårsager øjenirritation

Ansvarsfraskrivelse

De ovenstående oplysninger er baseret på vores nuværende viden, og de menes at være nøjagtige. Da oplysningerne muligvis anvendes under forhold, der ligger uden for vores kontrol og til hvilke vi ikke har noget kendskab, påtager vi os ikke noget ansvar for resultaterne af brugen af disse, og enhver, der får disse oplysninger, skal selv træffe en beslutning vedrørende virkninger, egenskaber, beskyttelse og bortskaffelse, der er gældende for denne persons særlige forhold. Der gives ingen garanti, hverken udtrykt eller underforstået (herunder en garanti af produktets salgbarhed eller egnethed til et bestemt formål) med hensyn til materialerne, nøjagtigheden af disse oplysninger, de resultater, der opnås fra brugen af disse, eller farer forbundet med brugen af materialet. Der skal udvises forsigtighed ved håndtering og brug af materialet. De ovenstående oplysninger er givet i god tro og med den opfattelse, at de er nøjagtige. Fra udgivelsesdatoen har vi stillet alle relevante oplysninger til rådighed vedrørende den forudsigelige håndtering af materialet. I tilfælde af en utilsigtet hændelse i forbindelse med produktet træder dette sikkerhedsdatablad imidlertid ikke i stedet for, og er ikke ment som, en erstatning for rådgivning fra uddannet personale.

Forkortelser:
NDA = No data available (Ingen data)

Sicherheitsdatenblatt
Inkrafttretensdatum: Januar 2021
Ersetzt (Datum): September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Abschnitt 1: Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktname	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Produktcode	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Relevante identifizierte Verwendungen der Substanz oder Mischung und Verwendungen, von denen abgeraten wird

Relevante identifizierte Verwendung(en)	Laborgebrauch

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US: techsupport@cepheid.com
	Telefon (Zentrale)	1 (888) 838-3222 - US Option 2
	Telefon (Zentrale)	1 (408) 541-4191 - außerhalb der USA
Lieferant		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Schweden www.cepheidinternational.com EU: support@cepheideurope.com
	Telefon (Zentrale)	+33 563 825 319
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australien www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefon (Australien)	1800 107 884

1.4 Notrufnummer

Hersteller	1 (800) 535-5053 - INFOTRAC - 24-Stunden-Notruf
Hersteller	1 (352) 323-3500 - außerhalb der USA

Abschnitt 2: Mögliche Gefahren

EU/EEC

Nach: Regulation (EC) Nr. 1272/2008 (CLP)/REACH 1907/2006 [geändert durch 453/2010]

2.1 Einstufung des Stoffs oder Gemischs

CLP

Das folgende SDB gilt für das Fertiggemischprodukt nur, wenn es im Labor benutzt wird. Das Produkt enthält Kügelchen und Reagenzien, die in der Kartusche oder in separaten Behältern vorhanden sind. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Nicht klassifiziert

2.2 Kennzeichnungselemente

CLP

Gefahrenhinweise Kein(e) Beschriftungselement(e) erforderlich

2.3 Sonstige Gefahren

CLP

Nach Verordnung (EG) Nr. 1272/2008 (CLP) gilt dieses Material nicht als gefährlich.

UN GHS (Inhalt der auf den Produkten verwendeten Etiketten)

Nach: Global harmonisiertes System der Einstufung und Kennzeichnung von Chemikalien (GHS) der UN

2.1 Einstufung des Stoffs oder Gemischs

UN GHS

Akute Toxizität, oral 5
Leichte Hautreizung 3
Leichte Augenreizung 2B

2.2 Kennzeichnungselemente

UN GHS

WARNHINWEIS

H-Sätze Gesundheitsschädlich bei Verschlucken
Möglicherweise gesundheitsschädlich bei Hautkontakt
Verursacht Augenreizung

P-Sätze

Vorbeugung Nach Gebrauch Hände gründlich waschen.

Reaktion Bei Hautreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen.

2.3 Sonstige Gefahren

UN GHS Nach dem global harmonisierten System zur Einstufung und Kennzeichnung (GHS) gilt dieses Produkt als gefährlich.

Vereinigte Staaten (VS)

Nach: OSHA 29 CFR 1910.1200 HCS

2.1 Einstufung des Stoffs oder Gemischs

OSHA HCS 2012 Leichte Augenreizung 2B

2.2 Kennzeichnungselemente

OSHA HCS 2012

Gefahrenhinweise Gesundheitsschädlich bei Verschlucken
Möglicherweise gesundheitsschädlich bei Hautkontakt
Verursacht Augenreizung

Sicherheitshinweise

Vorbeugung Nach Gebrauch Hände gründlich waschen.

Antwort BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

2.3 Sonstige Gefahren

OSHA HCS 2012 Nach den Vorschriften der USA (29 CFR 1910.1200 - Norm für Gefahrenkommunikation) gilt dieses Produkt nicht als gefährlich.

Kanada

Nach: WHMIS

2.1 Einstufung des Stoffs oder Gemischs

WHMIS Nicht klassifiziert

2.2 Kennzeichnungselemente

WHMIS Kein(e) Beschriftungselement(e) erforderlich.

2.3 Sonstige Gefahren

WHMIS In Kanada ist das oben genannte Produkt nach dem Workplace Hazardous Materials Information System (WHMIS) nicht als gefährlich einzustufen.

2.4 Sonstige Angaben

Alle anderen Reagenzien, Körner und andere Bestandteile sind in Konzentrationen unter 1 % im Gemisch vorhanden oder gelten nicht als gefährlich gemäß den US-Richtlinien für die Gefahrenkommunikation (29 CFR 1910.1200), den EU-Richtlinien für die Einstufung und Etikettierung von Substanzen oder Gemischen oder dem globalen Harmonisierungssystem für die Einstufung und Etikettierung von Substanzen oder Gemischen.

Abschnitt 3: Zusammensetzung/Angaben zu den Bestandteilen

3.1 Stoffe

Material erfüllt nicht die Kriterien einer Substanz.

3.2 Gemische

Zusammensetzung					
Chemische Bezeichnung	**Kennzeichnung**	**%**	**LD50/LC50**	**Klassifizierungen nach der Verordnung/Richtlinie**	**Bemerkungen**
Guanidiniumthiocyanat	**CAS:**593-84-0 **EINECS:** 209-812-1	10 %- 20 %	593 mg/kg	**EU CLP:** Akute Tox. 5, H302, H313, H320 **UN GHS:** Akute Tox. 5 (oral); Hautreizung 3; Augenreizung 2B **OSHA HCS 2012:** Akute Tox. 5 (oral); Augenreizung 2B	KDV

Abschnitt 4: Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Einatmen
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Verunfallten an die frische Luft bringen. Bei Atemschwierigkeiten Sauerstoffzufuhr einleiten. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat; künstliche Beatmung mit einer mit Einwegventil ausgestatteten Taschen-Sauerstoffmaske oder sonstigem geeigneten medizinischen Beatmungsgerät einleiten. Bei Atemstillstand künstliche Beatmung umgehend einleiten.

Haut
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei geringem Hautkontakt Material nicht auf andere Hautbereiche verteilen. Im Falle eines Hautkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Verunreinigte Kleidung entfernen und isolieren.

Augen
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Im Falle eines Augenkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Verschlucken
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei Einnahme Mund mit Wasser ausspülen (nur, wenn die Person bei Bewusstsein ist). KEIN Erbrechen herbeiführen. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat. Bei Einnahme sofort Arzt zu Rate ziehen.

4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen

Siehe Abschnitt 11 - Toxikologische Informationen.

4.3 Hinweis auf ärztliche Soforthilfe oder Spezialbehandlung

Hinweise für den Arzt Alle Behandlungsmaßnahmen sollten auf den beobachteten Anzeichen und Symptomen von Erschöpfung beim Patienten basieren. Außerdem ist zu berücksichtigen, dass es möglicherweise zum Kontakt mit anderen Materialien zusätzlich zu diesem Produkt kam.

Abschnitt 5: Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel GROSSBRAND: Trockenlöschmittel, CO2, alkoholresistenter Schaum oder Wasserstrahl.
KLEINBRAND: Trockenlöschmittel, CO2 oder Wasserstrahl.

Ungeeignete Löschmittel Keine Daten verfügbar

5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren

Ungewöhnliche Brand-und Explosionsgefahren Die Plastikkartusche enthält Reagenzien, die toxische Kohlenoxid-, Schwefeloxid- und Stickstoffoxiddämpfe abgeben können.

Gefährliche Verbrennungsprodukte Keine Daten verfügbar

5.3 Hinweise für die Brandbekämpfung

Für die Feuerbekämpfung vorgesehene Standardarbeitsschutzbekleidung bietet einen begrenzten Schutz NUR in Brandfällen; sie ist ineffektiv bei Verschüttungen, wo ein direkter Kontakt mit dem Stoff möglich ist.
Chemikalienschutzbekleidung tragen, die speziell vom Hersteller empfohlen wird. Sie kann wenig oder keinen Thermoschutz bieten.
Umgebungsluftunabhängiges Atemschutzgerät (SCBA) für Überdruckbetrieb tragen.
KLEINBRAND: Behälter aus der Brandzone entfernen, wenn es kein Risiko darstellt.

Abschnitt 6: Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Persönliche Schutzmaßnahmen Wenn eine Kartusche bricht, dann sind diese persönlichen Vorkehrungen anzuwenden. Entsprechende Schutzkleidung tragen. Nicht durch das verschüttete Material hindurch gehen. Beschädigte Behälter oder verschüttetes Material ohne geeignete Schutzkleidung nicht anfassen. Geschlossene Räume be- oder entlüften.

Sofortmaßnahmen Es sind keine Notfallmaßnahmen erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird.

6.2 Umweltschutzmaßnahmen

Nicht in Gewässer, die Kanalisation, Keller oder enge Räume gelangen lassen.

6.3 Methoden und Material für Rückhaltung und Reinigung

Einkapselung/Aufräumarbeiten Bei kleinen Verschüttungen Handschuhe tragen und Verschüttung mit einem Papiertuch aufnehmen. Verschüttetes Material nicht durch den Abfluss entsorgen.

6.4 Verweis auf andere Abschnitte

Siehe Abschnitt 8 - Einwirkungskontrolle/Personenschutz und Abschnitt 13 - Überlegungen zur Entsorgung.

Abschnitt 7: Handhabung und Lagerung

7.1 Schutzmaßnahmen zur sicheren Handhabung

Handhabung Keine spezielle Handhabung notwendig. Wenn eine Kartusche gebrochen ist, dann ist der Kontakt mit verschütteten Reagenzien zu vermeiden. Kontakt mit Haut und Augen vermeiden.

7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Umweltverträglichkeiten

Lagerung Produkt gemäß der Etikettierung lagern. Von nicht kompatiblem Material fernhalten. Unter Verschluss aufbewahren. Behälter/Verpackung dicht verschlossen an kühlem, gut belüftetem Ort lagern.

7.3 Spezifische Endanwendungen

Siehe Abschnitt 1.2 - Relevante identifizierte Nutzung.

Abschnitt 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstung

8.1 Zu überwachende Parameter

	Expositionsgrenzwerte/Richtlinien			
	Ergebnis	**ACGIH**	**NIOSH**	**OSHA**
Guanidiniumthiocyanat	TWA	Nicht ermittelt	Nicht ermittelt	Nicht ermittelt

8.2 Begrenzung und Überwachung der Exposition

Technische Maßnahmen/Kontrollen Es ist eine gute allgemeine Belüftung anzuwenden. Die Belüftungszahl sollte den Bedingungen entsprechen. Ggf. Prozesskammern, lokale Abzugsanlage oder andere technische Kontrollmittel verwenden, um die Konzentration in der Luft unter den empfohlenen Grenzwerten zu halten. Wenn keine Grenzwerte festgelegt wurden, sind die Konzentrationen auf einem akzeptablen Niveau zu halten.

Persönliche Schutzausrüstung

Atemwege Es wird nicht erwartet, dass Atemschutzgeräte erforderlich sind, sofern das Material unter normalen Bedingungen und wie empfohlen benutzt wird. Ansonsten die OSHA-Vorgaben für Atemschutzgeräte aus 29 CFR 1910.134 oder der Europäischen Norm EN 149 befolgen. Nach NIOSH/MSHA oder der europäischen Norm EN 149 zugelassenes Atemschutzgerät benutzen, wenn die Grenzwerte überschritten werden oder Symptome auftreten.

Augen/Gesicht Schutzbrillen gegen Chemikalienspritzer tragen.

Haut/Körper Schutzkleidung tragen

Umweltkontrollmaßnahmen Beste Praktiken bei Bauleitung und Abfallentsorgung anwenden.

Schlüssel für Abkürzungen
OSHA = Agentur für Sicherheit und Gesundheitsschutz am Arbeitsplatz
TWA = Zeitlich gewichtete Mittelwerte basieren auf einer Exposition von 8 Stunden/Tag, 40 Stunden/Woche

Abschnitt 9: Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Materialbeschreibung			
Physische Gestalt	Flüssigkeit	Farbe	Farblos
Geruch	Geruchlos	Geruchsschwelle	Fehlende Daten
Allgemeine Eigenschaften			
Siedepunkt	100 °C (212 °F)	Schmelzpunkt/Gefrierpunkt	0 °C (32 °F)
Zersetzungstemperatur	Fehlende Daten	pH	3,3 bis 8,8
Spezifisches Gewicht/Relative Dichte	= 1 Wasser=1	Wasserlöslichkeit	Löslich 100 %
Viskosität	Fehlende Daten	Explosive Eigenschaften	Fehlende Daten
Oxidationseigenschaften:	Fehlende Daten		
Volatilität			
Dampfdruck	Minimal	Dampfdichte	Fehlende Daten
Verdunstungsrate	Minimal		
Entflammbarkeit			
Flammpunkt	Fehlende Daten	Obere Expositionsgrenze	Fehlende Daten
Untere Expositionsgrenze	Fehlende Daten	Selbstzündung	Fehlende Daten
Entflammbarkeit (Feststoff, Gas)	Fehlende Daten		
Umwelt			
Oktanol/Wasser-Verteilungskoeffizient	Fehlende Daten		

9.2 Sonstige Angaben

Keine zusätzlichen physikalischen und chemischen Parameter vermerkt.

Abschnitt 10: Stabilität und Reaktivität

10.1 Reaktivität

Keine gefährliche Reaktion bekannt unter Bedingungen der normalen Verwendung.

10.2 Chemische Stabilität

Stabil

10.3 Möglichkeit gefährlicher Reaktionen

Eine gefährliche Polymerisierung findet nicht statt.

10.4 Zu vermeidende Bedingungen

Inkompatibles Material. Eine brennende Plastikkartusche, die Reagenzien enthält, kann toxische Nebenprodukte freisetzen.

10.5 Unverträgliche Materialien

Säuren.

10.6 Gefährliche Zersetzungsprodukte

Eine brennende Plastikkartusche, die Reagenzien enthält, kann toxische Nebenprodukte freisetzen.

Abschnitt 11: Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

Bestandteile		
Guanidiniumthiocyanat	593-84-0	**Akute Toxizität:** Intraperitoneal-Maus LD50 • 593 mg/kg

GHS Eigenschaften	Klassifizierung
Akute Toxizität	**EU/CLP**•Fehlende Daten **UN GHS**•Akute Toxizität - Verschlucken - Kategorie 5 **OSHA HCS 2012**•Fehlende Daten
Hautätzende Wirkung/Reizung	**EU/CLP**•Fehlende Daten **UN GHS**•Leichte Reizung der Haut Kategorie 3 **OSHA HCS 2012**•Fehlende Daten
Schwere Augenschäden/Augenreizung	**EU/CLP**•Fehlende Daten **UN GHS**• Leichte Augenreizung Kategorie 2B **OSHA HCS 2012**•Leichte Augenreizung Kategorie 2B
Hautsensibilisierung	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Sensibilisierung der Atemwege	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Karzinogenität	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Keimzell-Mutagenität	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Reproduktionstoxizität	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-SE	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

Mögliche gesundheitliche Auswirkungen

Einatmen

Akut (Sofort) Kann Reizung verursachen.
Chronisch (Verzögert) Keine Daten verfügbar

Haut

Akut (Sofort) Verursacht leichte Hautreizung.
Chronisch (Verzögert) Keine Daten verfügbar

Augen

Akut (Sofort) Verursacht Augenreizungen.
Chronisch (Verzögert) Keine Daten verfügbar

Verschlucken

Akut (Sofort) Kann bei Verschlucken schädlich sein.
Chronisch (Verzögert) Keine Daten verfügbar

Schlüssel für Abkürzungen
LD = Letale Dosierung

Abschnitt 12: Umweltbezogene Angaben

12.1 Toxizität

LC50 (Guppy): 89,1 mg/l; 96 h

12.2 Persistenz und Abbaubarkeit

Materialdaten fehlen.

12.3 Bioakkumulationspotential

Materialdaten fehlen.

12.4 Mobilität im Boden

Materialdaten fehlen.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Es wurde keine PBT- oder vPvB-Bewertung durchgeführt.

12.6 Andere schädliche Wirkungen

Es wurden keine Studien gefunden.

Abschnitt 13: Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Produktanwendung	Entsorgen von Inhalten und / oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und / oder internationalen Vorschriften.
Verpackungsabfall	Entsorgen von Inhalten und / oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und / oder internationalen Vorschriften.

13.2 Sonstige Angaben

Biologische Proben, Transfervorrichtungen und gebrauchte Kartuschen sind als infektiös anzusehen und mit den üblichen Vorsichtsmaßnahmen zu handhaben. Halten Sie sich bezüglich der angemessenen Entsorgung gebrauchter Kartuschen und nicht verwendeter Reagenzien an die Umweltschutzvorschriften Ihrer Einrichtung. Diese Materialien können chemischen Sondermüll darstellen, der gemäß bestimmten nationalen oder regionalen Vorgehensweisen entsorgt werden muss. Falls die Vorschriften des jeweiligen Landes oder der jeweiligen Region keine klaren Anweisungen zur ordnungsgemäßen Entsorgung enthalten, sollten biologische Proben und gebrauchte Kartuschen gemäß den Richtlinien der WHO (Weltgesundheitsorganisation) zur Handhabung und Entsorgung von medizinischen Abfällen entsorgt werden.

Abschnitt 14: Angaben zum Transport

	14.1 UN-Nummer	14.2 Korrekte UN-Bezeichnung des Frachtgutes	14.3 Transportgefahrenklasse(n)	14.4 Verpackungsgruppe	14.5 Umweltrisiken
DOT	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend
TDG	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend
IMO/IMDG	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend
IATA/ICAO	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend

14.6 Besondere Vorsichtsmaßnahmen für den Verwender

Keine Angaben.

14.7 Massengutbeförderung gemäß Anhang II des MARPOL-Übereinkommens 73/78 und gemäß IBC-Code

Nicht relevant.

Abschnitt 15: Rechtsvorschriften

15.1 Vorschriften zur Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

SARA – Klassifizierung von Gefahren Akut

Inventar						
Bauelemente	**CAS**	**Kanada NDSL**	**Kanada DSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidiniumthiocyanat	593-84-0	Ja	Nein	Ja	Nein	Ja

Kanada

Arbeit

Kanada - WHMIS – Klassifizierung von Substanzen

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kanada - WHMIS – Kanadische Offenbarungsliste der Inhaltsstoffe (IDL)

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Umwelt

Kanada - CEPA – Liste prioritärer Stoffe

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten

Arbeit

USA - OSHA - Prozesssicherheitsmanagement - Hochgefährliche Chemikalien

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - OSHA - Speziell regulierte Chemikalien

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Umwelt

USA - CAA (Clean Air Act) - 1990 Gefährliche Schadstoffe in der Luft

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA – Gefährliche Stoffe und deren meldepflichtige Mengen

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Radionuklide und ihre berichtspflichtigen Mengen

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302: Äußerst gefährliche Stoffe EPCRA RQ-Werte

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302: Äußerst gefährliche Stoffe TPQ-Werte

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA – Abschnitt 313 - Emissionsmeldung

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 – Verzeichnis von PBT-Chemikalien

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien

Umwelt

Kalifornien - Proposition 65 – Liste der krebserzeugenden Stoffe

›Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kalifornien - Proposition 65 - Entwicklungstoxizität

›Guanidiniumthiocyanat	593-84-0	*Nicht* gelistet

Kalifornien - Proposition 65 – Maximal zulässige Dosierungen (MADL)

›Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kalifornien - Proposition 65 – Ohne Nennenswerte Risiken (NSRL)

›Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kalifornien - Proposition 65 – Weibliche Reproduktionstoxizität

›Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kalifornien - Proposition 65 – Männliche Reproduktionstoxizität

›Guanidiniumthiocyanat	593-84-0	Nicht gelistet

15.2 Stoffsicherheitsbeurteilung

Es wurde keine chemische Sicherheitsanalyse durchgeführt.

Abschnitt 16: Sonstige Angaben

Relevante Sätze (Code & Volltext)

H302 – Gesundheitsschädlich beim Verschlucken
H313 – Möglicherweise gesundheitsschädlich bei Hautkontakt
H320 – Verursacht Augenreizung

Haftungsausschluss/ Angaben zur Haftung

Die obigen Informationen basieren auf Daten, die uns verfügbar sind und die wir für korrekt halten. Da die Informationen unter Bedingungen angewendet werden können, die außerhalb unserer Kontrolle liegen und mit denen wir möglicherweise nicht vertraut sind, übernehmen wir keine Verantwortung für die Ergebnisse der Nutzung und alle Personen, die sie erhalten, müssen ihre eigenen Festlegungen bezüglich der Wirkungen, Eigenschaften, Schutzmaßnahmen und Entsorgung vornehmen, die zu den jeweiligen Bedingungen gehören. Es wird keine Zusicherung, Gewährleistung oder Garantie, weder in ausdrücklicher noch in implizierter Form (einschließlich einer Garantie für die Eignung oder Handelsüblichkeit), erteilt werden im Hinblick auf die Stoffe, die Genauigkeit dieser Informationen, die Ergebnisse, die aus deren Nutzung resultieren, oder die Gefahren, die mit der Nutzung des Stoffes verbunden sind. Bei der Handhabung und Nutzung des Stoffs ist Vorsicht anzuwenden. Die obigen Informationen wurden nach bestem Wissen angegeben und für akkurat gehalten. Zum Datum der Ausstellung bieten wir alle Informationen, die für die zu erwartende Handhabung des Stoffs relevant sind. Bei einem Vorfall mit diesem Produkt stellt dieses Sicherheitsdatenblatt keinen Ersatz für die Rücksprache mit entsprechend geschultem Personal dar und ist nicht dazu gedacht.

Schlüssel für Abkürzungen
KDV = Keine Daten verfügbar

Ficha de datos de seguridad
Fecha de entrada en vigor: Enero 2021
Sustituye a fecha: Septiembre 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Sección 1 – Identificación de la sustancia/mezcla del proyecto/empresa

1.1 Identificador del producto

Nombre del producto	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Código del producto	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Usos identificados de la sustancia o mezcla y usos no recomendados

Usos identificados	Uso en laboratorio

1.3 Detalles del proveedor de la ficha de datos de seguridad

Fabricante	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Estados Unidos www.cepheid.com EE. UU.: techsupport@cepheid.com
Teléfono (general)	1 (888) 838-3222 - EE. UU. (opción 2)
Teléfono (general)	1 (408) 541-4191 - Fuera de EE. UU.
Proveedor	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Suecia www.cepheidinternational.com EU: support@cepheideurope.com
Teléfono (general)	+33 563 825 319
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
Teléfono (Australia)	1800 107 884

1.4 Número de teléfono de emergencia

Fabricante	1 (800) 535-5053 - INFOTRAC - Emergencia (24 h)
Fabricante	1 (352) 323-3500 - Fuera de EE. UU.

Sección 2 – Identificación de riesgos

UE/CEE

De acuerdo con: Reglamento (CE) Nº 1272/2008 (CLP)/REACH 1907/2006 [modificado por 453/2010]

2.1 Clasificación de la sustancia o mezcla

CLP

La siguiente FDS atañe solo al producto mezclado acabado final según se utiliza en el laboratorio. El producto contiene microesferas y reactivos en el cartucho o en los contenedores externos. Las exenciones a la divulgación de parte de la información de los componentes son conformes con el artículo CLP 1(5)(d) y 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
No clasificado

2.2 Elementos de la etiqueta

CLP

Declaraciones de riesgo No se requieren elementos de etiquetado

2.3 Otros riesgos

CLP

De acuerdo con el Reglamento (CE) Nº 1272/2008 (CLP), este material no se considera peligroso.

SGA de la ONU (Contenido del etiquetado utilizado en los productos)

De acuerdo con: Sistema Globalmente Armonizado (SGA) de Clasificación y Etiquetado de Productos Químicos de la ONU

2.1 Clasificación de la sustancia o mezcla

SGA de la ONU

Toxicidad oral aguda 5
Irritación leve de la piel 3
Irritación ocular leve 2B

2.2 Elementos de la etiqueta

SGA de la ONU

ADVERTENCIA

Declaraciones de riesgo

Nocivo en caso de ingestión
Puede ser nocivo en contacto con la piel
Provoca irritación ocular

Declaraciones preventivas

Prevención Lávese exhaustivamente las manos después de la manipulación.

Respuesta En caso de irritación cutánea: Consultar a un médico.
EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando.
Si persiste la irritación ocular: Consultar a un médico.
Llamar a un CENTRO DE INFORMACION TOXICOLOGICA o a un médico en caso de malestar.

2.3 Otros riesgos

SGA de la ONU — De acuerdo con el Sistema Globalmente Armonizado de Clasificación y Etiquetado de Productos Químicos (SGA), este producto se considera peligroso.

Estados Unidos (EE. UU.)
De acuerdo con: OSHA 29 CFR 1910.1200 HCS

2.1 Clasificación de la sustancia o mezcla

HCS 2012 de la OSHA — Irritación ocular leve 2B

2.2 Elementos de la etiqueta

HCS 2012 de la OSHA

Declaraciones de riesgo
Nocivo en caso de ingestión
Puede ser nocivo en contacto con la piel
Provoca irritación ocular

Declaraciones preventivas

Prevención — Lávese exhaustivamente las manos después de la manipulación.

Respuesta — EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando.
Si persiste la irritación ocular: Consultar a un médico.

2.3 Otros riesgos

HCS 2012 de la OSHA — De acuerdo con el reglamento de los Estados Unidos (29 CFR 1910.1200 - Estándar de Comunicación de Riesgos), este producto no se considera peligroso.

Canadá
De acuerdo con: WHMIS

2.1 Clasificación de la sustancia o mezcla

WHMIS — No clasificado

2.2 Elementos de la etiqueta

WHMIS — No se requieren elementos de etiquetado.

2.3 Otros riesgos

WHMIS — El producto mencionado no se considera peligroso en Canadá, de acuerdo con el Sistema de Información de Materiales Peligrosos en el Lugar de Trabajo (WHMIS).

2.4 Información adicional

Todos los demás reactivos, microesferas y otros constituyentes presentan concentraciones inferiores al 1 % en la mezcla y no se consideran peligrosos según los reglamentos de comunicación de riesgos de EE. UU. (29 CFR 1910.1200), las directivas para la clasificación y el etiquetado de sustancias y mezclas de la UE y el Sistema Globalmente Armonizado de clasificación y etiquetado de sustancias y mezclas.

Sección 3 – Composición/información de los ingredientes

3.1 Sustancias

El material no cumple con los criterios de clasificación de sustancias.

3.2 Mezclas

Composición					
Nombre del producto químico	**Identificadores**	**%**	**LD50/LC50**	**Clasificaciones de acuerdo con el reglamento/directiva**	**Comentarios**
Tiocianato de guanidina	**CAS:** 593-84-0 **EINECS:** 209-812-1	10 % – 20 %	593 mg/kg	**CLP UE:** Tox. aguda 5, H302, H313, H320 **SGA de la ONU:** Tox. aguda 5 (oral); Irrit. cutánea 3; Irrit. ocular 2B **HCS 2012 de la OSHA:** Tox. aguda 5 (oral); Irrit. ocular 2B	No hay datos disponibles

Sección 4 – Medidas de primeros auxilios

4.1 Descripción de las medidas de primeros auxilios

Inhalación No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Traslade a la persona al aire libre. Si la respiración resulta difícil, administre oxígeno. No utilice el método de boca a boca si la víctima ha inhalado la sustancia; proporcione respiración artificial con la ayuda de una máscara de bolsillo equipada con una válvula de una sola vía u otro dispositivo médico de respiración adecuado. Si la persona no respira, proporcione respiración artificial.

Piel No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Ante un contacto menor con la piel, evite la difusión den material sobre la piel no afectada. Si entra en contacto con la sustancia, enjuague inmediatamente la piel con agua durante al menos 20 minutos. Retire y aísle la ropa contaminada.

Ojo No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Si entra en contacto con la sustancia, enjuague inmediatamente los ojos con agua durante al menos 20 minutos. Si persiste la irritación ocular: Consultar a un médico.

Ingestión No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. En caso de ingestión, enjuague la boca con agua (solo si la persona está consciente). NO provoque el vómito. No utilice el método de boca a boca si la víctima ha ingerido la sustancia. En caso de ingestión, solicite atención médica inmediatamente.

4.2 Síntomas y efectos más importantes, tanto agudos como retardados

Consulte la Sección 11 - Información toxicológica.

4.3 Indicación de cualquier atención médica inmediata y tratamiento especial necesarios

Notas para el médico Todos los tratamientos deben basarse en señales y síntomas observados en el paciente. Considere si puede haberse producido una sobreexposición a otros materiales distintos de este producto.

Sección 5 – Medidas antiincendios

5.1 Medios de extinción

Medios de extinción adecuados	INCENDIOS MAYORES: Polvo químico seco, CO2, espuma resistente al alcohol o agua pulverizada. INCENDIOS MENORES: Polvo químico seco, CO2 o agua pulverizada.
Medios de extinción inadecuados	No hay datos disponibles

5.2 Riesgos especiales procedentes de la sustancia o mezcla

Riesgos de incendio y explosión inusuales	El cartucho de plástico que contiene reactivos puede emitir vapores tóxicos de óxidos de carbono, óxidos de azufre y óxidos de nitrógeno.
Productos de combustión peligrosa	No hay datos disponibles

5.3 Consejos para el personal antiincendios

El traje de protección estándar del personal antiincendios proporciona protección limitada EXCLUSIVAMENTE contra el fuego; no resulta efectivo ante vertidos donde es posible el contacto directo con la sustancia.
Utilice un traje de protección química específicamente recomendado por el fabricante. Puede proporcionar poca o ninguna protección térmica.
Utilice un equipo de respiración autónomo (ERA) de presión positiva.
INCENDIOS MENORES: Mueva los contenedores del área del incendio si la operación no conlleva riesgos.

Sección 6 – Medidas en caso de liberación accidental

6.1 Precauciones personales, equipamiento protector y procedimientos de emergencia

Precauciones personales	En caso de romperse un cartucho, pueden aplicarse estas precauciones personales. Utilice un traje de protección adecuado. No camine a través del material vertido. No toque los contenedores dañados ni los materiales vertidos a menos que utilice un traje de protección adecuado. Ventile las áreas cerradas.
Procedimientos de emergencia	Se espera que no sea necesario aplicar procedimientos de emergencia si el material se utiliza bajo condiciones normales y del modo recomendado.

6.2 Precauciones medioambientales

Evite la entrada en alcantarillas, vías fluviales, sótanos y espacios cerrados.

6.3 Métodos y materiales de contención y limpieza

Medidas de contención/ limpieza	Para vertidos menores, utilice guantes y absorba el vertido con una toalla de papel. No deseche materiales vertidos por el desagüe.

6.4 Referencia a otras secciones

Consulte la Sección 8 - Controles de exposición/protección personal y la Sección 13 - Consideraciones de eliminación.

Sección 7 – Manipulación y almacenamiento

7.1 Precauciones para la manipulación segura

Manipulación No se necesita ninguna manipulación especial. En caso de romperse un cartucho, evite el contacto con los reactivos vertidos. Evite el contacto con la piel y los ojos.

7.2 Condiciones para el almacenamiento seguro, incluidas posibles incompatibilidades

Almacenamiento Almacénelos de acuerdo con las indicaciones de su etiqueta. Mantenga el producto alejado de materiales incompatibles. Guardar bajo llave. Mantenga el contenedor/embalaje bien cerrado en un lugar fresco y ventilado.

7.3 Usos finales específicos

Consulte la Sección 1.2 - Usos identificados relevantes.

Sección 8 – Control de exposición / protección personal

8.1 Parámetros de control

	Directrices/límites de exposición			
	Resultado	**ACGIH**	**NIOSH**	**OSHA**
Tiocianato de guanidinio	TWA	No establecido	No establecido	No establecido

8.2 Controles de exposición

Controles/medidas de ingeniería Es necesaria una buena ventilación general. La tasa de ventilación debe corresponder a las condiciones. Si es posible, utilice recintos de procesamiento, ventilación local u otros controles de ingeniería para mantener los niveles del aire por debajo de los límites de exposición recomendados. Si los límites de exposición no se han establecido, mantenga los niveles del aire a un nivel aceptable.

Equipo de protección individual

Respiratorios No se prevé la necesidad de disponer de equipo respiratorio si el material se utiliza en condiciones normales y de la forma recomendada. De lo contrario, siga los reglamentos para máscaras de la OSHA incluidas en el estándar 29 CFR 1910.134 o en el estándar europeo EN 149. Utilice una máscara aprobada por la NIOSH/MSHA o la norma europea EN 149 si se superan los límites de exposición o se experimentan síntomas.

Ocular/facial Utilice gafas de protección contra salpicaduras químicas.

Piel/cuerpo Utilice un traje de protección

Controles de exposición en el medio ambiente Siga las buenas prácticas para administrar el centro y eliminar residuos.

Clave de abreviaturas
OSHA = Administración de Seguridad y Salud Ocupacional
TWA = Los promedios de tiempo ponderado se basan en exposiciones durante 8 h/día y 40 h/semana

Sección 9 – Propiedades físicas y químicas

9.1 Información sobre las propiedades físicas y químicas

Descripción del material			
Forma física	Líquido	Color	Incoloro
Olor	Inodoro	Umbral de olor	Faltan datos
Propiedades generales			
Punto de ebullición	100 °C (212 °F)	Punto de fusión / punto de congelación	0 °C (32 °F)
Temperatura de descomposición	Faltan datos	pH	3,3 a 8,8
Gravedad específica / densidad relativa	= 1 Agua =1	Hidrosolubilidad	Soluble 100 %
Viscosidad	Faltan datos	Propiedades explosivas	Faltan datos
Propiedades oxidantes:	Faltan datos		
Volatilidad			
Presión del vapor	Mínima	Densidad del vapor	Faltan datos
Tasa de evaporación	Mínima		
Inflamabilidad			
Punto de inflamación	Faltan datos	UEL	Faltan datos
LEL	Faltan datos	Autoignición	Faltan datos
Inflamabilidad (sólido, gas)	Faltan datos		
Medioambiental			
Coeficiente de reparto octanol/agua	Faltan datos		

9.2 Información adicional

No se han anotado parámetros físicos o químicos adicionales.

Sección 10 – Estabilidad y reactividad

10.1 Reactividad

No se conocen reacciones peligrosas bajo condiciones normales de uso.

10.2 Estabilidad del producto químico

Estable

10.3 Posibilidad de reacciones peligrosas

No ocurrirá polimerización peligrosa.

10.4 Condiciones que deben evitarse

Materiales incompatibles. El cartucho de plástico quemado que contiene reactivos puede liberar subproductos tóxicos.

10.5 Materiales incompatibles

Ácidos.

10.6 Productos de descomposición peligrosos

El cartucho de plástico quemado que contiene reactivos puede liberar subproductos tóxicos.

Sección 11 – Información toxicológica

11.1 Información sobre efectos toxicológicos

Componentes		
Tiocianato de guanidinio	593-84-0	**Toxicidad aguda:** Intraperitoneal-Ratón LD50 • 593 mg/kg

Propiedades del SGA	Clasificación
Toxicidad aguda	**CLP/UE**•Faltan datos **SGA de la ONU**•Toxicidad aguda - Oral - Categoría 5 **HCS 2012 de la OSHA**•Faltan datos
Corrosión/irritación dérmica	**CLP/UE**•Faltan datos **SGA de la ONU**•Irritación dérmica leve - Categoría 3 **HCS 2012 de la OSHA**•Faltan datos
Daño/irritación ocular grave	**CLP/UE**•Faltan datos **SGA de la ONU**•Irritación ocular leve - Categoría 2B **HCS 2012 de la OSHA**•Irritación ocular leve - Categoría 2B
Sensibilización dérmica	**CLP/UE**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Sensibilización respiratoria	**CLP/UE**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Carcinogenicidad	**CLP/UE**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Mutagenicidad de células germinales	**CLP/UE**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Toxicidad para la reproducción	**CLP/UE**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-SE	**CLP/UE**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos

Efectos potenciales en la salud

Inhalación
Agudo (inmediato) Puede causar irritación.
Crónico (retardado) No hay datos disponibles
Piel
Agudo (inmediato) Causa irritación leve en la piel.
Crónico (retardado) No hay datos disponibles
Ojo
Agudo (inmediato) Causa irritación ocular.
Crónico (retardado) No hay datos disponibles
Ingestión
Agudo (inmediato) Ingestión posiblemente dañina.
Crónico (retardado) No hay datos disponibles

Clave de abreviaturas
LD = Dosis letal

Sección 12 – Información ecológica

12.1 Toxicidad

LC50 (guppy): 89,1 mg/l a 96 h

12.2 Persistencia y degradabilidad

Faltan datos de material.

12.3 Potencial bioacumulativo

Faltan datos de material.

12.4 Movilidad en el suelo

Faltan datos de material.

12.5 Resultados de la evaluación de PBT y mPmB

No se ha realizado ninguna valoración de PBT y mPmB.

12.6 Otros efectos adversos

No se han encontrado estudios.

Sección 13 – Consideraciones sobre la eliminación

13.1 Métodos de tratamiento de residuos

Residuos de productos	Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.
Residuos de embalaje	Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

13.2 Información adicional

Las muestras biológicas, los dispositivos de transferencia y los cartuchos usados deben ser considerados capaces de transmitir agentes infecciosos que requieren las precauciones habituales. Siga los procedimientos de eliminación de residuos medioambientales de su centro para la eliminación adecuada de los cartuchos usados y los reactivos no utilizados. Estos materiales pueden presentar características propias de los residuos químicos peligrosos, que requieren procedimientos específicos de eliminación de carácter nacional o regional. Si las normativas nacionales o regionales no proporcionan instrucciones claras en cuanto a los procedimientos de eliminación adecuados, las muestras biológicas y los cartuchos utilizados deben desecharse de conformidad con las directrices de la OMS (Organización Mundial de la Salud) en cuanto a la manipulación y eliminación de desechos médicos.

Sección 14 – Información de transporte

	14.1 Número ONU	14.2 Designación oficial de transporte de la ONU	14.3 Clases de riesgo de transporte	14.4 Grupo de embalaje	14.5 Riesgos para el medioambiente
DOT	No regulado	No regulado	No regulado	No regulado	No aplicable
TDG	No regulado	No regulado	No regulado	No regulado	No aplicable
IMO/IMDG	No regulado	No regulado	No regulado	No regulado	No aplicable
IATA/ICAO	No regulado	No regulado	No regulado	No regulado	No aplicable

14.6 Precauciones especiales para el usuario

Ninguno especificado.

14.7 Transporte a granel de acuerdo con el Anexo II del MARPOL 73/78 y el código IBC

Irrelevante

Sección 15 – Información reglamentaria

15.1 Legislación/reglamentos de seguridad, salud y medio ambiente específicos para la sustancia o mezcla

Clasificaciones de riesgo de la ley SARA Agudo

Inventario						
Componente	**CAS**	**DSL de Canadá**	**NDSL de Canadá**	**EINECS de la UE**	**ELNICS de la UE**	**TSCA**
Tiocianato de guanidinio	593-84-0	Sí	No	Sí	No	Sí

Canadá

Mano de obra

Canadá - WHMIS - Clasificación de sustancias
- Tiocianato de guanidinio 593-84-0 No listado

Canadá - WHMIS - Lista de divulgación de ingredientes
- Tiocianato de guanidinio 593-84-0 No listado

Medio ambiente

Canadá - CEPA - Lista de sustancias prioritárias
- Tiocianato de guanidinio 593-84-0 No listado

Estados Unidos

Mano de obra

EE. UU. - OSHA - Administración de seguridad de procesos - Productos químicos muy peligrosos
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - OSHA - Productos químicos regulados de manera específica
- Tiocianato de guanidinio 593-84-0 No listado

Medio ambiente

EE. UU. - CAA (Clean Air Act) - 1990 Contaminantes peligrosos del aire
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - CERCLA/SARA - Sustancias peligrosas y sus cantidades declarables
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - CERCLA/SARA - Radionucleidos y sus cantidades declarables
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades declarables de sustancias extremadamente peligrosas según la EPCRA
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades para la planificación de umbrales de sustancias extremadamente peligrosas
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - CERCLA/SARA - Sección 313 - Informes de emisión
- Tiocianato de guanidinio 593-84-0 No listado

EE. UU. - CERCLA/SARA - Sección 313 - Lista de productos químicos PBT
- Tiocianato de guanidinio 593-84-0 No listado

Estados Unidos - California

Medio ambiente

EE. UU. - California - Proposición 65 - Lista de productos cancerígenos		
•Tiocianato de guanidinio	593-84-0	No listado
EE. UU. - California - Proposición 65 - Toxicidad en el desarrollo		
•Tiocianato de guanidinio	593-84-0	*No listado*
EE. UU. - California - Proposición 65 - Niveles máximos de dosis permitidos (MADL)		
•Tiocianato de guanidinio	593-84-0	No listado
EE. UU. - California - Proposición 65 - Sin niveles de riesgo significativos (NSRL)		
•Tiocianato de guanidinio	593-84-0	No listado
EE. UU. - California - Proposición 65 - Toxicidad en la reproducción – Mujeres		
•Tiocianato de guanidinio	593-84-0	No listado
EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Hombres		
•Tiocianato de guanidinio	593-84-0	No listado

15.2 Evaluación de seguridad del producto químico

No se ha llevado a cabo ninguna evaluación de seguridad química.

Sección 16 – Información adicional

Frases pertinentes (código y texto completo)

H302 – Nocivo en caso de ingestión
H313 – Puede ser nocivo en contacto con la piel
H320 – Provoca irritación ocular

Declaración/ descargo de responsabilidad

La información anterior está basada en los datos que tenemos y la consideramos correcta. Debido a que la información puede aplicarse bajo condiciones externas a nuestro control y con las que podemos no estar familiarizados, no asumimos ninguna responsabilidad por los resultados de su uso, y todas las personas que la reciban deberán determinar por sí mismas los efectos, propiedades, protecciones y eliminación correspondientes a sus condiciones particulares. No se efectúa ninguna representación ni garantía, expresa o implícita (incluida ninguna garantía de adecuación o comerciabilidad para un objetivo concreto) respecto a los materiales, la precisión de esta información, los resultados obtenidos de su uso ni los riesgos relacionados con dicho uso del material. Tenga precaución al manipular y utilizar el material. La información superior se considera precisa y se ofrece de buena fe. Proporcionamos toda la información relacionada con la manipulación prevista del material en la fecha de publicación. Sin embargo, en caso de ocurrir un incidente adverso asociado a este producto, esta ficha de datos de seguridad no es ni debe utilizarse como sustituto de la consulta con personal formado adecuadamente.

Clave de abreviaturas
NDA = No hay datos disponibles

Fiche signalétique
Date d'entrée en vigueur : Janvier 2021
Remplace la date : Septembre 2020

Xpert Flu/RSV XC ; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV ; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Section 1: Identification de la substance/du mélange et de la compagnie/entreprise

1.1 Identifiant de produit

Nom du produit	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu ; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Code de produit	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Utilisations pertinentes identifiées de la substance ou du mélange et utilisations contre-indiquées

Utilisations pertinentes identifiées	Utilisation en laboratoire

1.3 Coordonnées du fournisseur de la fiche signalétique

Fabricant	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US : techsupport@cepheid.com
Téléphone (général)	1 (888) 838-3222 - États-Unis Choix 2
Téléphone (général)	1 (408) 541-4191 - En dehors des États-Unis
Fournisseur	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Suède www.cepheidinternational.com EU : support@cepheideurope.com
Téléphone (général)	+33 563 825 319
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australie www.cepheidinternational.com ANZ : TechSupportANZ@cepheid.com
Téléphone (Australie)	1800.107.884

1.4 Numéro de téléphone d'urgence

Fabricant	1 (800) 535-5053 - INFOTRAC - Urgences 24 h/24
Fabricant	1 (352) 323-3500 - En dehors des États-Unis

Section 2 : Identification des risques

EU/EEC

Selon : Règlement (CE) N° 1272/2008 (CLP)/REACH 1907/2006 [modifié par le 453/2010]

2.1 Classification de la substance ou mélange

CLP

La présente fiche de données de sécurité (FDS) concerne uniquement le produit de mélange fini final, tel qu'utilisé au laboratoire. Le produit contient des billes et des réactifs dans la cartouche ou dans des conteneurs externes. Les exemptions à la divulgation de l'information concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et à la norme 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

CLP

Mentions de danger Aucun élément d'étiquette requis

2.3 Autres dangers

CLP

Selon le règlement (CE) n° 1272/2008 (CLP), ce produit n'est pas considéré dangereux.

SGH ONU (Contenu de l'étiquetage utilisé sur les produits)

Selon : Système général harmonisé (SGH) des Nations Unies concernant la classification et l'étiquetage des produits chimiques

2.1 Classification de la substance ou mélange

Mentions de danger SGH (classification)

Toxicité aiguë par voie orale 5
Légère irritation cutanée 3
Légère irritation oculaire 2B

2.2 Éléments de l'étiquette

SGH ONU

ATTENTION

Mentions de danger

Nocif en cas d'ingestion
Peut être nocif par contact avec la peau
Provoque une irritation des yeux

Mises en garde

Prévention Se laver les mains soigneusement après manipulation.

Réponse

En cas d'irritation cutanée : consulter un médecin.
EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer.
Si l'irritation oculaire persiste : consulter un médecin.
Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.

2.3 Autres dangers

SGH ONU Selon le Système général harmonisé de classification et d'étiquetage (SGH), ce produit est considéré dangereux.

États-Unis (US)

Selon : OSHA 29 CFR 1910.1200 HCS

2.1 Classification de la substance ou mélange

OSHA HCS 2012 Légère irritation oculaire 2B

2.2 Éléments de l'étiquette

OSHA HCS 2012

Mentions de danger
Nocif en cas d'ingestion
Peut être nocif par contact avec la peau
Provoque une irritation des yeux

Mises en garde

Prévention Se laver les mains soigneusement après manipulation.

Réponse EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer.
Si l'irritation oculaire persiste : consulter un médecin.

2.3 Autres dangers

OSHA HCS 2012 En vertu des réglementations des États-Unis (29 CFR 1910.1200 - Norme de communication des dangers), ce produit n'est pas considéré comme dangereux.

Canada

Selon : WHMIS

2.1 Classification de la substance ou mélange

WHMIS Non classé

2.2 Éléments de l'étiquette

WHMIS Aucune étiquette(s) requise.

2.3 Autres dangers

WHMIS Au Canada, le produit mentionné ci-dessus n'est pas considéré dangereux en vertu du Système d'information sur les matières dangereuses utilisées au travail (SIMDUT).

2.4 Autres informations

Tous les autres réactifs, les billes et autres constituants sont à des concentrations inférieures à 1% dans le mélange ou ne sont pas considérés dangereux selon la réglementation américaine sur la communication des dangers (29 CFR 1910.1200), selon les directives de l'UE concernant la classification et l'étiquetage des substances et des mélanges, ou selon le système international d'harmonisation pour la classification et l'étiquetage des substances ou des mélanges.

Section 3 : Composition/informations sur les ingrédients

3.1 Substances

La matière ne répond pas aux critères d'une substance.

3.2 Mélanges

Composition					
Nom chimique	**Identifiants**	**%**	**LD50/LC50**	**Classifications selon réglementation/directive**	**Commentaires**
Thiocyanate de guanidinium	**CAS :** 593-84-0 **EINECS :** 209-812-1	10 %-20 %	593 mg/kg	**UE CLP :** Tox. aiguë 5, H302, H313, H320 **SGH ONU :** Tox. aiguë 5 (voie orale) ; irrit. cutanée 3; irrit. yeux 2B **OSHA HCS 2012 :** Tox. aiguë 5 (voie orale) ; irrit. yeux 2B	ADD

Section 4 : Premiers soins

4.1 Description des premiers soins

Inhalation Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. Déplacer la victime à l'air frais. Administrer de l'oxygène si la respiration est difficile. Ne pas faire de bouche-à-bouche si la victime a inhalé la substance ; pratiquer la respiration artificielle à l'aide d'un masque de poche doté d'une valve unidirectionnelle ou d'un autre dispositif médical respiratoire approprié. Pratiquer la respiration artificielle si la victime ne respire pas.

Peau Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact cutané mineur, éviter de répandre la matière sur la peau non affectée. En cas de contact avec la substance, rincer immédiatement la peau à l'eau courante pendant au moins 20 minutes. Retirer et isoler les vêtements contaminés.

Yeux Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact avec la substance, rincer immédiatement les yeux à l'eau courante pendant au moins 20 minutes. Si l'irritation oculaire persiste : consulter un médecin.

Ingestion Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas d'ingestion, rincer la bouche avec de l'eau (seulement si la victime est consciente). NE PAS faire vomir. Ne pas faire de bouche-à-bouche si la victime a ingéré la substance. Consulter immédiatement un médecin en cas d'ingestion.

4.2 Symptômes et effets les plus importants, aigus et différés

Voir la section 11 - Informations toxicologiques.

4.3 Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires

Notes pour le médecin Tous les traitements doivent être basés sur les signes et symptômes de détresse observés chez le patient. Il faut envisager la possibilité d'une surexposition à d'autres matières que ce produit.

Section 5 : Mesures de lutte contre l'incendie

5.1 Agents extincteurs

Agent extincteur convenable	INCENDIES MAJEURS : poudre sèche, CO2, mousse antialcool ou eau pulvérisée. INCENDIES MINEURS : poudre sèche, CO2, ou eau pulvérisée.
Agent extincteur inapproprié	Aucune donnée disponible

5.2 Dangers particuliers résultant de la substance ou du mélange

Dangers inhabituels d'incendie et d'explosion	La cartouche en plastique contenant des réactifs peut émettre des vapeurs toxiques d'oxydes de carbone, d'oxydes de soufre et d'oxydes d'azote.
Produits de combustion dangereux	Aucune donnée disponible

5.3 Conseils aux pompiers

Les vêtements structurels de protection des pompiers fournissent une protection limitée UNIQUEMENT en cas d'incendie ; ils ne sont pas efficaces dans les cas de déversement où le contact direct avec la substance est possible.
Porter des vêtements de protection chimique spécifiquement recommandés par le fabricant. Ceux-ci peuvent fournir peu ou pas de protection thermique.
Porter un appareil respiratoire autonome à pression positive (ARA).
INCENDIES MINEURS : enlever les conteneurs de la zone d'incendie si vous pouvez le faire sans risque.

Section 6 : Mesures en cas de fuite accidentelle

6.1 Précautions individuelles, équipement de protection et mesures d'urgence

Précautions individuelles	Dans le cas où une cartouche est percée, ces précautions individuelles s'appliquent. Porter les vêtements de protection appropriés. Ne pas marcher à travers la matière déversée. Ne pas toucher les conteneurs endommagés ou la matière déversée sauf en cas de port de vêtements de protection appropriés. Ventiler les espaces clos.
Mesures d'urgence	Aucune procédure d'urgence ne devrait s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations.

6.2 Précautions environnementales

Prévenir la pénétration dans les cours d'eau, les égouts, les sous-sols ou les endroits confinés.

6.3 Méthodes et matériaux de confinement et de nettoyage

Mesures de confinement/de nettoyage	Pour les petits déversements, porter des gants et absorber la matière déversée avec une serviette en papier. Ne pas jeter la matière déversée dans les égouts.

6.4 Référence à d'autres sections

Voir la section 8 - Contrôles de l'exposition/Protection personnelle, ainsi que la section 13 - Considérations de mise au rebut.

Section 7 : Manutention et stockage

7.1 Précautions pour une manutention sans danger

Manutention Aucune manipulation spéciale n'est nécessaire. Si une cartouche est percée, éviter tout contact avec les réactifs déversés. Éviter tout contact avec la peau et les yeux.

7.2 Conditions de sécurité du stockage, y compris toutes incompatibilités

Stockage Stocker conformément à l'étiquetage des produits. Tenir à l'écart des matières incompatibles. Garder sous clef. Conserver le conteneur/emballage hermétiquement fermé dans un endroit frais et bien aéré.

7.3 Utilisations finales spécifiques

Voir la section 1.2 - Utilisations pertinentes identifiées.

Section 8 : Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

	Limites d'exposition/Lignes directrices			
	Résultat	**ACGIH**	**NIOSH**	**OSHA**
Thiocyanate de guanidinium	Moyenne pondérée en fonction du temps (TWA)	Non établi	Non établi	Non établi

8.2 Contrôles d'exposition

Mesures/contrôles techniques Une bonne ventilation générale doit être utilisée. Les débits de ventilation doivent être adaptés aux conditions. Le cas échéant, utiliser des enceintes d'isolement, une ventilation aspirante locale ou d'autres moyens techniques pour maintenir les concentrations atmosphériques en dessous des limites d'exposition recommandées. Si les limites d'exposition n'ont pas été établies, maintenir les concentrations atmosphériques à un niveau acceptable.

Équipement de protection individuelle

Respiratoire Un équipement respiratoire ne devrait pas s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations. Sinon, suivre les réglementations de l'OSHA relatives aux appareils respiratoires définies dans 29 CFR 1910.134 ou la norme européenne EN 149. Utiliser un appareil respiratoire approuvé par le NIOSH/MSHA ou la norme européenne EN 149 si les limites d'exposition sont dépassées ou des symptômes apparaissent.

Yeux/visage Porter des lunettes anti-éclaboussures contre les produits chimiques.

Peau/corps Porter des vêtements de protection

Contrôle d'exposition lié à la protection de l'environnement Suivre les bonnes pratiques pour la gestion de site et l'élimination des déchets.

Clef aux abréviations
OSHA = Administration de la sécurité et de la santé au travail
TWA = Les moyennes pondérées dans le temps sont basées sur des expositions de 8 h/jour, 40 h/semaine

Section 9 : Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques

Description de la matière			
Forme physique	Liquide	Couleur	Incolore
Odeur	Inodore	Seuil d'odeur	Manque de données
Propriétés générales			
Point d'ébullition	100 °C (212 °F)	Point de fusion/Point de congélation	0 °C (32 °F)
Température de décomposition	Manque de données	pH	3,3 à 8,8
Densité spécifique/relative	=1/Eau=1	Solubilité dans l'eau	Soluble à 100 %
Viscosité	Manque de données	Propriétés explosives	Manque de données
Propriétés comburantes :	Manque de données		
Volatilité			
Pression de vapeur	Minime	Densité de vapeur	Manque de données
Taux d'évaporation	Minime		
Inflammabilité			
Point d'éclair	Manque de données	LSE	Manque de données
LIE	Manque de données	Auto-inflammation	Manque de données
Inflammabilité (solide, gaz) :	Manque de données		
Environnemental(e)			
Coefficient de partage octanol/eau	Manque de données		

9.2 Autres informations

Aucun paramètre physique ou chimique supplémentaire noté.

Section 10 : Stabilité et réactivité

10.1 Réactivité

Pas de réactions dangereuses connues dans des conditions normales d'utilisation.

10.2 Stabilité chimique

Stable

10.3 Possibilité de réactions dangereuses

Il ne se produira pas de polymérisation dangereuse.

10.4 Conditions à éviter

Matières incompatibles. Si l'on brûle une cartouche en plastique contenant des réactifs, des sous-produits toxiques peuvent être libérées.

10.5 Matériaux incompatibles

Acides.

10.6 Produits de décomposition dangereux

Si l'on brûle une cartouche en plastique contenant des réactifs, des sous-produits toxiques peuvent être libérées.

Section 11 : Information toxicologique

11.1 Informations sur les effets toxiques

Composants		
Thiocyanate de guanidinium	593-84-0	**Toxicité aiguë :** Voie intrapéritonéale-Souris LD50 • 593 mg/kg

Propriétés GHS	Classification
Toxicité aiguë	**UE/CLP**•Manque de données **SGH ONU**•Toxicité aiguë - Ingestion/Oral - Catégorie 5 **OSHA HCS 2012**•Manque de données
Corrosion/irritation cutanée	**UE/CLP**•Manque de données **SGH ONU**•Légère irritation cutanée Catégorie 3 **OSHA HCS 2012**•Manque de données
Lésion/irritation grave des yeux	**UE/CLP**•Manque de données **SGH ONU**•Légère irritation oculaire Catégorie 2B **OSHA HCS 2012**•Légère irritation oculaire Catégorie 2B
Sensibilisation cutanée	**UE/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Sensibilisation respiratoire	**UE/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Cancérogénicité	**UE/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Mutagénicité de cellule germinale	**UE/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Toxicité pour la reproduction	**UE/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-SE	**UE/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données

Effets éventuels sur la santé

Inhalation
Aigu (immédiat) Peut provoquer une irritation.
Chronique (différé) Aucune donnée disponible
Peau
Aigu (immédiat) Provoque une légère irritation cutanée.
Chronique (différé) Aucune donnée disponible
Yeux
Aigu (immédiat) Provoque une irritation des yeux.
Chronique (différé) Aucune donnée disponible
Ingestion
Aigu (immédiat) Peut être nocif en cas d'ingestion.
Chronique (différé) Aucune donnée disponible

Clef aux abréviations
LD = Dose létale

Section 12 : Information écologique

12.1 Toxicité

CL50 (guppy) : 89,1 mg/l à 96 h

12.2 Persistance et dégradabilité

Manque de données matérielles.

12.3 Potentiel bioaccumulatif

Manque de données matérielles.

12.4 Mobilité dans le sol

Manque de données matérielles.

12.5 Résultats des évaluations PBT et vPvB

Aucune évaluation PBT ou vPvB n'a été réalisée.

12.6 Autres effets nocifs

Aucune étude n'a été trouvée.

Section 13 : Considérations de mise au rebut

13.1 Méthodes de traitement des déchets

Déchets du produit	Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.
Conditionnement des déchets	Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

13.2 Autres informations

Les échantillons biologiques, les dispositifs de transfert et les cartouches usagées doivent être considérés comme étant susceptibles de transmettre des agents infectieux exigeant des précautions standard. Suivre les consignes environnementales d'élimination des déchets établies par l'établissement pour l'élimination appropriée des cartouches usagées et des réactifs non utilisés. Ces matériaux peuvent présenter des caractéristiques de déchets chimiques dangereux exigeant des procédures d'élimination spécifiques au niveau national ou régional. En l'absence de directives claires de la réglementation nationale ou régionale sur l'élimination appropriée, les échantillons biologiques et les cartouches usagées doivent être éliminés conformément aux directives de manipulation et d'élimination des déchets médicaux de l'OMS (Organisation Mondiale de la Santé).

Section 14 : Informations de transport

	14.1 Numéro ONU	14.2 Nom d'expédition des Nations Unies	14.3 Classe(s) de danger pour le transport	14.4 Groupe d'emballage	14.5 Dangers pour l'environnement
DOT	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet
TDG	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet
IMO/IMDG	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet
IATA/ICAO	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet

14.6 Précautions spéciales pour l'utilisateur

Rien de précisé.

14.7 Transport en vrac conformément à l'annexe II de la convention Marpol 73/78 et au recueil IBC

Sans objet.

Section 15 : Informations réglementaires

15.1 Réglementation relative à la sécurité, la santé et l'environnement/ législation spécifique à la substance ou au mélange

Classifications de dangers SARA Aiguë

Inventaire						
Composant	**CAS**	**LIS du Canada**	**LES du Canada**	**EU EINECS**	**UE ELNICS**	**TSCA**
Thiocyanate de guanidinium	593-84-0	Oui	Non	Oui	Non	Oui

Canada

Travail

Canada - SIMDUT - Classifications des substances
•Thiocyanate de guanidinium 593-84-0 Non énuméré

Canada - SIMDUT - Liste de divulgation des ingrédients
• Thiocyanate de guanidinium 593-84-0 Non énuméré

Environnement

Canada - LCPE - Liste des substances prioritaires
• Thiocyanate de guanidinium 593-84-0 Non énuméré

États-Unis

Travail

É.-U. - OSHA - Gestion de la sécurité des procédés - Produits chimiques très dangereux
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - OSHA - Produits chimiques spécifiquement réglementés
• Thiocyanate de guanidinium 593-84-0 Non énuméré

Environnement

É.-U. - CAA (Clean Air Act) - 1990 Polluants atmosphériques dangereux
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - CERCLA/SARA - Substances dangereuses et leurs quantités à déclarer
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - CERCLA/SARA - Radionucléides et leurs quantités à déclarer
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses QR EPCRA
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses TPQ
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Rapports sur les émissions
• Thiocyanate de guanidinium 593-84-0 Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Liste des produits chimiques PBT
• Thiocyanate de guanidinium 593-84-0 Non énuméré

Etats-Unis - Californie

Environnement

É.-U. - Californie - Proposition 65 - Liste des substances cancérigènes		
• Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour le développement		
• Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Doses maximales admissibles (MADL)		
• Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Niveaux de risque non significatifs (NSRL)		
• Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Femme		
• Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Homme		
• Thiocyanate de guanidinium	593-84-0	Non énuméré

15.2 Évaluation de sécurité chimique

Aucune évaluation de sécurité chimique n'a été effectuée.

Section 16 : Autres informations

Phrases pertinentes (code et texte entier)

H302 - Nocif en cas d'ingestion.
H313 - Peut être nocif par contact avec la peau
H320 - Provoque une irritation des yeux

Déclaration de non-responsabilité

Les informations ci-dessus reposent sur les données dont nous disposons et que nous jugeons correctes. Dans la mesure où ces informations peuvent être utilisées dans des conditions hors de notre contrôle et que nous ne connaissons pas nécessairement, nous n'assumons aucune responsabilité pour les conséquences de leur utilisation et toutes les personnes recevant le produit doivent en déterminer personnellement les effets, les propriétés, ainsi que les mesures de protection et d'élimination nécessaires en rapport avec leurs conditions d'utilisation particulières. Aucune représentation, garantie ou assurance, explicite ou implicite (y compris une garantie d'aptitude ou de qualité marchande pour un but particulier) n'est faite concernant les produits, l'exactitude des informations, les résultats découlant de leur utilisation ou les risques liés à l'utilisation du produit. Il y a lieu de faire preuve de prudence lors de la manipulation et de l'utilisation du produit. Les informations ci-dessus sont fournies en toute bonne foi et avec la conviction qu'elles sont exactes. À la date de publication, nous fournissons toutes les informations pertinentes pour la manipulation prévisible du produit. Cependant, dans l'éventualité d'un incident associé à l'utilisation de ce produit, cette fiche de données de sécurité ne peut pas (et n'est pas conçue pour) se substituer à l'avis d'un personnel correctement formé.

Clef aux abréviations
ADD = Pas de données disponibles

Sigurnosno-tehnički list
Datum stupanja na snagu: siječnja 2021.
Zamjenjuje datum: rujan 2020.

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Odjeljak 1: Identifikacija tvari/smjese i tvrtke/poduzeća

1.1 Označitelj proizvoda

Naziv proizvoda	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Šifra proizvoda	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Relevantne identificirane namjene tvari ili smjese i upotrebe koje se ne preporučuju

Relevantne identificirane namjene	Laboratorijska namjena

1.3 Pojedinosti o dobavljaču sigurnosno-tehničkog lista

Proizvođač		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Sjedinjene Države www.cepheid.com SAD: techsupport@cepheid.com
	Telefon (opći)	+1 (888) 838-3222 - SAD Opcija 2
	Telefon (opći)	+1 (408) 541-4191 - izvan SAD-a
Dobavljač		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Švedska www.cepheidinternational.com EU: support@cepheideurope.com
	Telefon (opći)	+33 563 825 319
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australija www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefon (Australija)	1800 107 884

1.4 Telefonski broj za hitne slučajeve

Proizvođač	+1 (800) 535-5053 - INFOTRAC - 24-satni broj za hitne slučajeve
Proizvođač	+1 (352) 323-3500 - izvan SAD-a

Sigurnosno-tehnički list
Datum stupanja na snagu: siječnja 2021.
Zamjenjuje datum: rujan 2020.

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Odjeljak 2: Identifikacija opasnosti

EU/EEZ

U skladu s: Uredbom (EZ) br. 1272/2008 (CLP)/REACH 1907/2006 [izmijenjena Uredbom 453/2010]

2.1 Razvrstavanje tvari ili smjesa

CLP

Sljedeći sigurnosno-tehnički list (SDS) namijenjen je samo za konačnu gotovu smjesu kako se koristi u laboratoriju. Proizvod sadrži kuglice i reagense u ulošku ili vanjskim spremnicima. Izuzeci za otkrivanje podataka o nekim sastavnicama sukladni su s Člankom o CLP-u 1(5)(d) i 29 CFR 1910.1200(g)(2)(i)(C)(1) i (2).
Nije razvrstano

2.2 Elementi označavanja

CLP

Oznake upozorenja Nisu potrebni elementi označavanja

2.3 Ostale opasnosti

CLP U skladu s Uredbom (EZ) br. 1272/2008 (CLP) ovaj se materijal ne smatra opasnim.

UN GHS (Sadržaj označavanja koji se koristi na proizvodima)

U skladu s: Globalno usklađenim sustavom razvrstavanja i označavanja kemikalija (GHS) Ujedinjenih naroda

2.1 Razvrstavanje tvari ili smjesa

UN GHS

Akutna oralna toksičnost 5
Blagi nadražaj kože 3
Blagi nadražaj oka 2B

2.2 Elementi označavanja

UN GHS

UPOZORENJE

Oznake upozorenja

Štetno ako se proguta
Može biti štetno u dodiru s kožom
Uzrokuje nadražaj oka

Oznake obavijesti

Prevencija Nakon rukovanja proizvodom temeljito oprati ruke.

Reakcija Ako dođe do nadraživanja kože: potražite liječničku pomoć.
U SLUČAJU DODIRA S OČIMA: pažljivo ispirite vodom nekoliko minuta.
Skinuti kontaktne leće, ako ih nosite i ako se lako skidaju. Nastaviti ispiranje.
Ako nadražaj oka ne prestaje: potražite liječničku pomoć.
Ako se ne osjećate dobro, nazovite CENTAR ZA TROVANJA ili liječnika.

2.3 Ostale opasnosti

UN GHS Prema Globalno usklađenom sustavu razvrstavanja i označavanja kemikalija (GHS) ovaj se proizvod smatra opasnim.

Sjedinjene Države (SAD)
U skladu s: OSHA 29 CFR 1910.1200 HCS

2.1 Razvrstavanje tvari ili smjesa

OSHA HCS 2012 Blagi nadražaj oka 2B

2.2 Elementi označavanja

OSHA HCS 2012

Oznake upozorenja Štetno ako se proguta
Može biti štetno u dodiru s kožom
Uzrokuje nadražaj očiju

Oznake obavijesti

Prevencija Nakon rukovanja proizvodom temeljito oprati ruke.

Reakcija U SLUČAJU DODIRA S OČIMA: pažljivo ispirite vodom nekoliko minuta.
Skinuti kontaktne leće, ako ih nosite i ako se lako skidaju. Nastaviti ispiranje.
Ako nadražaj oka ne prestaje: potražite liječničku pomoć.

2.3 Ostale opasnosti

OSHA HCS 2012 Prema Propisima Sjedinjenih Država (29 CFR 1910.1200 - Standardi informiranja o opasnostima) ovaj se proizvod ne smatra opasnim.

Kanada
U skladu s: WHMIS

2.1 Razvrstavanje tvari ili smjesa

WHMIS Nije razvrstano

2.2 Elementi označavanja

WHMIS Nisu potrebni elementi označavanja.

2.3 Ostale opasnosti

WHMIS U Kanadi se gore navedeni proizvod ne smatra opasnim prema Informacijskom sustavu o opasnim materijalima na radnom mjestu (WHMIS).

2.4 Ostale informacije

Svi ostali reagensi, kuglice i drugi sastojci prisutni su u koncentraciji manjoj od 1 % u smjesama ili se ne smatraju opasnima prema američkim propisima o priopćavanju opasnosti (29 CFR 1910.1200), direktivama EU-a za razvrstavanje i označavanje tvari ili smjesa ili Globalno usklađenom sustavu za razvrstavanje i označavanje tvari ili smjesa.

Odjeljak 3: Sastav/Informacije o sastojcima

3.1 Tvari

Materijal ne ispunjava kriterije tvari.

3.2 Smjese

Sastav					
Kemijski naziv	**Označitelji**	**%**	**LD50/LC50**	**Razvrstavanje u skladu s Uredbom/Direktivom**	**Komentari**
Gvanidin tiocijanat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10 % - 20 %	593 mg/kg	**EU CLP:** Akutno toks. 5, H302, H313, H320 **UN GHS:** Akutno toks. 5 (Orl); nadraž. kože 3; nadraž. oka 2B **OSHA HCS 2012:** Akutno toks. 5 (Orl); nadraž. oka 2B	NDP

Odjeljak 4: Mjere prve pomoći

4.1 Opis mjera prve pomoći

Udisanje Prva pomoć ne smatra se potrebnom ako se materijal koristi u uobičajenim uvjetima te kako se preporučuje. Premjestite unesrećenog na svježi zrak. U slučaju otežanog disanja dajte kisik. Ne upotrebljavajte metodu usta na usta ako je unesrećeni udahnuo tvar; pružite umjetno disanje pomoću džepne maske opremljene jednosmjernim ventilom ili drugog odgovarajućeg respiratornog medicinskog proizvoda. Ako unesrećeni ne diše, pružite umjetno disanje.

Koža Prva pomoć ne smatra se potrebnom ako se materijal koristi u uobičajenim uvjetima te kako se preporučuje. Kod manjih dodira s kožom pazite da ne proširite materijal na nezahvaćenu kožu. U slučaju dodira s tvari odmah isperite kožu tekućom vodom u trajanju od najmanje 20 minuta. Skinite i izolirajte kontaminiranu odjeću.

Oko Prva pomoć ne smatra se potrebnom ako se materijal koristi u uobičajenim uvjetima te kako se preporučuje. U slučaju dodira s tvari odmah isperite oči tekućom vodom u trajanju od najmanje 20 minuta. Ako nadražaj oka ne prestaje: potražite liječničku pomoć.

Gutanje Prva pomoć ne smatra se potrebnom ako se materijal koristi u uobičajenim uvjetima te kako se preporučuje. U slučaju gutanja isperite usta vodom (samo ako je osoba pri svijesti) NEMOJTE izazivati povraćanje. Ne upotrebljavajte metodu usta na usta ako je unesrećeni progutao tvar. U slučaju gutanja potražite hitnu liječničku pomoć.

4.2 Najvažniji simptomi i učinci, akutni i odgođeni

Proučite Odjeljak 11 - Toksikološke informacije.

4.3 Pokazatelj potrebe za hitnom liječničkom pomoći i posebnim postupanjem

Napomene za liječnika Svako postupanje treba se temeljiti na uočenim znakovima i simptomima patnje kod bolesnika. Potrebno je razmotriti mogućnost prekomjernog izlaganja nekim drugim materijalima osim ovog proizvoda.

Odjeljak 5: Mjere za gašenje požara

5.1 Sredstva za gašenje

Prikladna sredstva za gašenje	VELIKI POŽARI: Suhe kemikalije, CO2, pjena otporna na alkohol ili prskanje vode. MALI POŽARI: Suhe kemikalije, CO2 ili prskanje vode.
Neprikladna sredstva za gašenje	Nema dostupnih podataka

5.2 Posebne opasnosti koje proizlaze iz tvari ili smjese

Neuobičajene opasnosti od požara i eksplozije	Plastični spremnik koji sadrži reagense može ispuštati otrovne pare ugljikovih oksida, sumporovih oksida, dušikovih oksida.
Opasni proizvodi izgaranja	Nema dostupnih podataka

5.3 Savjeti za vatrogasce

Strukturna zaštitna odjeća vatrogasaca osigurava SAMO ograničenu zaštitu u slučaju požara; nije učinkovita u slučaju izlijevanja u kojem je moguć izravan dodir s tvari.
Nosite odjeću za zaštitu od kemikalija koju izričito preporučuje proizvođač. Ona pruža neznatnu termalnu zaštitu ili je uopće ne pruža.
Nosite samostalni aparat za disanje s pozitivnim tlakom (SCBA).
MALI POŽARI: Preselite spremnike s mjesta požara ako to možete učiniti na siguran način.

Odjeljak 6: Mjere kod slučajnog ispuštanja

6.1 Osobne mjere opreza, zaštitna oprema i postupci u hitnim slučajevima

Osobne mjere opreza	Ove se osobne mjere opreza primjenjuju u slučaju slomljenog uloška. Nosite odgovarajuću zaštitnu odjeću. Nemojte prolaziti kroz proliveni materijal. Nemojte dodirivati oštećene spremnike ili proliveni materijal ako ne nosite odgovarajuću zaštitnu odjeću. Prozračite zatvorene prostore.
Postupci u hitnim slučajevima	Hitna pomoć ne smatra se potrebnom ako se materijal koristi u uobičajenim uvjetima te kako se preporučuje.

6.2 Mjere zaštite okoliša

Spriječite ulazak u vodene tokove, kanalizaciju, podrume ili zatvorene prostore.

6.3 Metode i materijali za zadržavanje i čišćenje

Mjere zadržavanja/ čišćenja	Kod manjih izlijevanja nosite rukavice i počistite proliveni materijal upijajućim papirnatim ručnikom. Nemojte bacati prolivene materijale u odvod.

6.4 Reference na druge odjeljke

Proučite Odjeljak 8 - Nadzor nad izloženošću/Osobna zaštita i Odjeljak 13 - Zbrinjavanje.

Odjeljak 7: Rukovanje i skladištenje

7.1 Mjere opreza za sigurno rukovanje

Rukovanje Nisu potrebne posebne mjere opreza pri rukovanju. Izbjegavajte dodir s prolivenim reagensima ako je uložak slomljen. Izbjegavajte dodir s kožom i očima.

7.2 Uvjeti sigurnog skladištenja, uzimajući u obzir moguće inkompatibilnosti

Skladištenje Čuvajte u skladu s označavanjem proizvoda. Držite podalje od inkompatibilnih materijala. Čuvajte zaključanim. Držite spremnik/pakiranje dobro zatvorenim na hladnom i prozračnom mjestu.

7.3 Posebna krajnja namjena

Proučite Odjeljak 1.2 - Relevantne identificirane namjene.

Odjeljak 8: Nadzor nad izloženošću/Osobna zaštita

8.1 Kontrolni parametri

	Granične vrijednosti izlaganja/smjernice			
	Rezultat	**ACGIH**	**NIOSH**	**OSHA**
Gvanidin tiocijanat	TWA	Nije utvrđeno	Nije utvrđeno	Nije utvrđeno

8.2 Nadzor nad izloženošću

Tehnološke mjere/nadzor Potrebno je koristiti dobru opću ventilaciju. Učestalost ventilacije treba prilagoditi uvjetima. Ako je primjenjivo, koristite ograđeni prostor za obradu, lokalnu ispušnu ventilaciju i ostali tehnološki nadzor za održavanje razine čestica u zraku ispod preporučenih graničnih vrijednosti izlaganja. Ako granične vrijednosti izlaganja nisu utvrđene, održavajte razine čestica u zraku na prihvatljivoj razini.

Osobna zaštitna oprema

Za disanje Oprema za disanje ne smatra se potrebnom ako se materijal koristi u uobičajenim uvjetima te kako se preporučuje. U suprotnom, pridržavajte se propisa o respiratorima koje je izdala američka Uprava za zaštitu na radu (OSHA) iz odjeljka 29 CFR 1910.134 ili Europske norme EN 149. Koristite respirator koji je odobrio NIOSH/MSHA ili Europska norma EN 149 u slučaju prekoračenja graničnih vrijednosti izlaganja ili pojave simptoma.

Oči/lice Nosite zaštitne naočale sa zaštitom od prskanja kemikalija.

Koža/tijelo Nosite zaštitnu odjeću

Nadzor nad izloženošću okoliša Pridržavajte se najboljih postupaka za upravljanje lokacijom i odlaganje otpada.

Tumač kratica
OSHA = Uprava za zaštitu na radu
TWA = vremenski ponderirane prosječne vrijednosti temelje se na izlaganju od 8 sati/dan, 40 sati/tjedan

Odjeljak 9: Fizikalna i kemijska svojstva

9.1 Informacije o fizikalnim i kemijskim svojstvima

Opis materijala			
Fizikalni oblik	Tekućina	Boja	Bezbojna
Miris	Bez mirisa	Prag mirisa	Nedostaju podaci
Opća svojstva			
Točka vrelišta	100 °C (212 °F)	Točka tališta/točka ledišta	0 °C (32 °F)
Temperatura razgradnje	Nedostaju podaci	pH	3,3 do 8,8
Specifična težina/ relativna gustoća	= 1 voda=1	Topljivost u vodi	Topljivo 100 %
Viskoznost	Nedostaju podaci	Eksplozivna svojstva	Nedostaju podaci
Oksidacijska svojstva:	Nedostaju podaci		
Hlapljivost			
Tlak pare	Minimalni	Gustoća pare	Nedostaju podaci
Brzina isparavanja	Minimalni		
Zapaljivost			
Točka plamišta	Nedostaju podaci	Gornja granica eksplozivnosti (UEL)	Nedostaju podaci
Donja granica eksplozivnosti (LEL)	Nedostaju podaci	Samozapaljenje	Nedostaju podaci
Zapaljivost (krutih tvari, plinova)	Nedostaju podaci		
Okolišni			
Koeficijent raspodjele oktanol/voda	Nedostaju podaci		

9.2 Ostale informacije

Nisu uočeni dodatni fizikalni i kemijski parametri.

Odjeljak 10: Stabilnost i reaktivnost

10.1 Reaktivnost

Nisu poznate opasne reakcije u uvjetima uobičajene upotrebe.

10.2 Kemijska stabilnost

Stabilan

10.3 Mogućnost opasnih reakcija

Neće doći do opasne polimerizacije.

10.4 Uvjeti koje je potrebno izbjegavati

Inkompatibilni materijali. Spaljivanje plastičnih uložaka koji sadrže reagense može osloboditi toksične nusproizvode

10.5 Inkompatibilni materijali

Kiseline.

10.6 Opasni proizvodi razgradnje

Spaljivanje plastičnih uložaka koji sadrže reagense može osloboditi toksične nusproizvode.

Odjeljak 11: Toksikološke informacije

11.1 Informacije o toksikološkim učincima

Sastavnice		
Gvanidin tiocijanat	593-84-0	**Akutna toksičnost:** Intraperitonealno-miš LD50 • 593 mg/kg

Svojstva Globalno usklađenog sustava razvrstavanja i označavanja kemikalija (GHS)	**Razvrstavanje**
Akutna toksičnost	**EU/CLP**•Nedostaju podaci **UN GHS**•Akutna toksičnost - oralna 5 **OSHA HCS 2012**•Nedostaju podaci
Nagrizanje/nadražaj kože	**EU/CLP**•Nedostaju podaci **UN GHS**•Blagi nadražaj kože 3 **OSHA HCS 2012**•Nedostaju podaci
Ozbiljno oštećenje/nadražaj oka	**EU/CLP**•Nedostaju podaci **UN GHS**•Blagi nadražaj oka 2B **OSHA HCS 2012**•Blagi nadražaj oka 2B
Osjetljivost kože	**EU/CLP**•Nedostaju podaci **UN GHS**•Nedostaju podaci **OSHA HCS 2012**•Nedostaju podaci
Osjetljivost dišnog sustava	**EU/CLP**•Nedostaju podaci **UN GHS**•Nedostaju podaci **OSHA HCS 2012**•Nedostaju podaci
Karcinogenost	**EU/CLP**•Nedostaju podaci **UN GHS**•Nedostaju podaci **OSHA HCS 2012**•Nedostaju podaci
Mutagenost reproduktivnih stanica	**EU/CLP**•Nedostaju podaci **UN GHS**•Nedostaju podaci **OSHA HCS 2012**•Nedostaju podaci
Toksičnost za reprodukciju	**EU/CLP**•Nedostaju podaci **UN GHS**•Nedostaju podaci **OSHA HCS 2012**•Nedostaju podaci
STOT-SE	**EU/CLP**•Nedostaju podaci **UN GHS**•Nedostaju podaci **OSHA HCS 2012**•Nedostaju podaci

Mogući učinci na zdravlje

Udisanje
Akutni (trenutačni) Može izazvati nadražaj.
Kronični (odgođeni) Nema dostupnih podataka

Koža
Akutni (trenutačni) Izaziva blagi nadražaj kože.
Kronični (odgođeni) Nema dostupnih podataka

Oko
Akutni (trenutačni) Izaziva nadražaj očiju.
Kronični (odgođeni) Nema dostupnih podataka

Gutanje
Akutni (trenutačni) Može biti štetno ako se proguta.
Kronični (odgođeni) Nema dostupnih podataka

Tumač kratica
LD = smrtonosna doza (Lethal Dose)

Odjeljak 12: Ekološke informacije

12.1 Toksičnost

LC50 (ribica): 89,1 mg/l nakon 96 sati

12.2 Postojanost i razgradivost

Nedostaju materijalni podaci.

12.3 Bioakumulacijski potencijal

Nedostaju materijalni podaci.

12.4 Pokretljivost u tlu

Nedostaju materijalni podaci.

12.5 Rezultati procjene svojstava PBT i vPvB

Nije provedena procjena svojstava PBT i vPvB.

12.6 Drugi štetni učinci

Nisu pronađena ispitivanja.

Odjeljak 13: Zbrinjavanje

13.1 Metode zbrinjavanja otpada

Proizvodni otpad	Odložite sadržaj i/ili spremnik u otpad u skladu s lokalnim, regionalnim, nacionalnim i/ili međunarodnim propisima.
Ambalažni otpad	Odložite sadržaj i/ili spremnik u otpad u skladu s lokalnim, regionalnim, nacionalnim i/ili međunarodnim propisima.

13.2 Ostale informacije

Biološki uzorci, prijenosni pribor i iskorišteni ulošci trebaju se smatrati sposobnima za prijenos uzročnika zaraznih bolesti te su potrebne standardne mjere opreza. Za pravilno odlaganje iskorištenih uložaka i neiskorištenih reagensa slijedite postupke za upravljanje otpadom svoje ustanove. Ti materijali mogu pokazivati značajke opasnog kemijskog otpada, za što su potrebni posebni nacionalni ili regionalni postupci za odlaganje. Ako nacionalni ili regionalni propisi ne pružaju jasne upute o pravilnom odlaganju, biološki uzorci i iskorišteni ulošci trebaju se odložiti prema smjernicama za rukovanje medicinskim otpadom i njegovo odlaganje Svjetske zdravstvene organizacije (World Health Organization, WHO).

Odjeljak 14: Informacije o prijevozu

	14.1 UN broj	14.2 Pravilno otpremno ime prema UN-u	14.3 Razred(i) opasnosti pri prijevozu	14.4 Pakirna skupina	14.5 Opasnosti za okoliš
DOT	Nije uređeno	Nije uređeno	Nije uređeno	Nije uređeno	Nije primjenjivo
TDG	Nije uređeno	Nije uređeno	Nije uređeno	Nije uređeno	Nije primjenjivo
IMO/IMDG	Nije uređeno	Nije uređeno	Nije uređeno	Nije uređeno	Nije primjenjivo
IATA/ICAO	Nije uređeno	Nije uređeno	Nije uređeno	Nije uređeno	Nije primjenjivo

14.6 Posebne mjere opreza za korisnika

Nisu navedene.

14.7 Prijevoz u rasutom stanju sukladno Prilogu II konvencije MARPOL 73/78 i IBC Kodeksa

Nije relevantno.

Odjeljak 15: Informacije o propisima

15.1 Propisi u području sigurnosti, zdravlja i okoliša/Posebni propisi za tvar ili smjesu

Razvrstavanje opasnosti prema Zakonu o izmjenama i dopunama te obnovi odobrenja programa Superfund (SARA) Akutne

Zalihe						
Sastavnica	**CAS**	**Kanada DSL**	**Kanada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Gvanidin tiocijanat	593-84-0	Da	Ne	Da	Ne	Da

Kanada

Labor

Kanada - WHMIS - Razvrstavanje tvari
•Gvanidin tiocijanat 593-84-0 Nije naveden
Kanada - WHMIS - Popis sastojaka
•Gvanidin tiocijanat 593-84-0 Nije naveden

Okoliš

Kanada - CEPA - Popis prioritetnih tvari
•Gvanidin tiocijanat 593-84-0 Nije naveden

Sjedinjene Države

Labor

SAD - OSHA - Upravljanje sigurnosti procesa - jako opasne kemikalije
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - OSHA - Posebno regulirane kemikalije
•Gvanidin tiocijanat 593-84-0 Nije naveden

Okoliš

SAD - CAA (Zakon o čistom zraku) - 1990 Opasne tvari koje onečišćuju zrak
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - CERCLA/SARA - Opasne tvari i njihove količine koje se moraju prijaviti
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - CERCLA/SARA - Radionuklidi i njihove količine koje se moraju prijaviti
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - CERCLA/SARA - Odjeljak 302 Količine vrlo opasnih tvari koje se moraju prijaviti prema zakonu EPCRA
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - CERCLA/SARA - Odjeljak 302 Količine planiranja praga za vrlo opasne tvari
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - CERCLA/SARA - Odjeljak 313 - Izvješćivanje o emisijama
•Gvanidin tiocijanat 593-84-0 Nije naveden
SAD - CERCLA/SARA - Odjeljak 313 - Popis kemikalija s postojanim, bioakumulativnim i toksičnim (PBT) karakteristikama
•Gvanidin tiocijanat 593-84-0 Nije naveden

Sjedinjene Države - Kalifornija

Okoliš

SAD - Kalifornija - Podnesak 65 - Popis karcinogena		
•Gvanidin tiocijanat	593-84-0	Nije naveden
SAD - Kalifornija - Podnesak 65 - Razvojna toksičnost		
•Gvanidin tiocijanat	593-84-0	*Nije naveden*
SAD - Kalifornija - Podnesak 65 - Najveće dopuštene razine doze (MADL)		
•Gvanidin tiocijanat	593-84-0	Nije naveden
SAD - Kalifornija - Podnesak 65 - Razine koje ne predstavljaju značajan rizik (NSRL)		
•Gvanidin tiocijanat	593-84-0	Nije naveden
SAD - Kalifornija - Podnesak 65 - Reproduktivna toksičnost - ženska		
•Gvanidin tiocijanat	593-84-0	Nije naveden
SAD - Kalifornija - Podnesak 65 - Reproduktivna toksičnost - muška		
•Gvanidin tiocijanat	593-84-0	Nije naveden

15.2 Procjena kemijske sigurnosti

Nije provedena procjena kemijske sigurnosti.

Odjeljak 16: Ostale informacije

Odgovarajuće oznake (oznaka i potpuni tekst)

H302 - štetno ako se proguta
H313 - može biti štetno u dodiru s kožom
H320 - uzrokuje nadražaj očiju

Izjava o odricanju odgovornosti/ Izjava o odgovornosti

Gore navedene informacije temelje se na nama dostupnim podacima i smatraju se točnima. Budući da se informacije mogu primijeniti u uvjetima izvan naše kontrole i s kojima nismo upoznati, ne preuzimamo nikakvu odgovornost za rezultate njegove upotrebe, a sve osobe koje ih primaju moraju same odrediti učinke, svojstva, mjere zaštite i odlaganje koji se odnose na njihove posebne uvjete. Ne daje se nikakvo zastupanje, jamstvo ili garancija, izričita ili podrazumijevana (uključujući jamstvo prikladnosti ili mogućnosti prodaje u određenu svrhu) po pitanju materijala, preciznosti tih podataka, rezultata dobivenih njihovom upotrebom ili opasnosti povezanih s upotrebom materijala. Potreban je oprez pri rukovanju materijalom i njegovoj upotrebi. Gore navedene informacije navedene su u dobroj namjeri i uvjerenju da su točne. Na datum izdavanja navodimo sve informacije koje su relevantne za predviđeno rukovanje materijalom. No u slučaju štetnih događaja koji se povezuju s ovim proizvodom, ovaj sigurnosno-tehnički list nije, niti je predviđen kao zamjena za savjetovanje s odgovarajuće obučenim osobljem.

Tumač kratica
NDP = nema dostupnih podataka

Scheda dati di sicurezza
Data di decorrenza: Gennaio 2021
Sostituisce la versione di: Settembre 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Sezione 1: Identificazione della sostanza/miscela e dell'azienda/impresa

1.1 Identificatore del prodotto

Nome prodotto	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Codice prodotto	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Usi pertinenti identificati della sostanza della miscela e utilizzi sconsigliati

Usi pertinenti identificati	Uso in laboratorio

1.3 Dettagli del fornitore della scheda dati di sicurezza

Produttore	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Stati Uniti www.cepheid.com USA: techsupport@cepheid.com
Telefono (generale)	1 (888) 838-3222 - USA Opzione 2
Telefono (generale)	1 (408) 541-4191 - Fuori dagli USA
Fornitore	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Svezia www.cepheidinternational.com EU: support@cepheideurope.com
Telefono (generale)	+33 563 825 319
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
Telefono (Australia)	1800 107 884

1.4 Numero telefonico di emergenza

Produttore	1 (800) 535-5053 - INFOTRAC - Numero telefonico di emergenza attivo 24 ore su 24
Produttore	1 (352) 323-3500 - Fuori dagli USA

Sezione 2: Identificazione dei pericoli

UE/CEE

In ottemperanza a: Normativa (CE) N.1272/2008 (CLP)/REACH 1907/2006 [emendata dalla 453/2010]

2.1 Classificazione della sostanza o della miscela

CLP

La seguente Scheda informativa in materia di sicurezza (SDS) è da considerarsi valida per il prodotto finito finale (miscela) solo se usato in laboratorio. Il prodotto contiene microsfere e reagenti all'interno della cartuccia oppure in contenitori esterni alla cartuccia. Le esenzioni dall'obbligo di comunicazione delle informazioni sui componenti sono conformi all'articolo 1(5)(d) del CLP e alla normativa 29 CFR 1910.1200(g)(2)(i)(C)(1)e(2).
Non classificato

2.2 Elementi dell'etichetta

CLP

Frasi di rischio Non è richiesta alcuna etichetta

2.3 Altri rischi

CLP

In base al Regolamento (CE) n. 1272/2008 (CLP), questo materiale non è considerato pericoloso.

UN GHS (Contenuto delle etichette utilizzate sui prodotti)

In ottemperanza a: Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN Globally Harmonized System of Classification and Labeling of Chemicals, GSH)

2.1 Classificazione della sostanza o della miscela

Dichiarazioni precauzionali UN GHS (Classificazione)

Tossicità acuta – Orale 5
Lieve irritazione cutanea 3
Lieve irritazione oculare 2B

2.2 Elementi dell'etichetta

UN GHS

ATTENZIONE

Indicazioni di pericolo

Nocivo se ingerito
Può essere nocivo per contatto con la pelle
Provoca irritazione oculare

Consigli di prudenza

Prevenzione Lavare accuratamente le mani dopo la manipolazione.

Risposta In caso di irritazione della pelle: consultare un medico.
IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
Se l'irritazione degli occhi persiste, consultare un medico.
In caso di malessere, contattare un CENTRO ANTIVELENI o un medico.

2.3 Altri rischi

UN GHS In conformità al Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN GHS) questo prodotto è considerato pericoloso.

Stati Uniti (USA)

In ottemperanza a: OSHA 29 CFR 1910.1200 HCS

2.1 Classificazione della sostanza o della miscela

OSHA HCS 2012 Lieve irritazione oculare 2B

2.2 Elementi dell'etichetta

OSHA HCS 2012

Indicazioni di pericolo
Nocivo se ingerito
Può essere nocivo per contatto con la pelle
Provoca irritazione oculare

Consigli di prudenza

Prevenzione Lavare accuratamente le mani dopo la manipolazione.

Risposta IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente con acqua per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
Se l'irritazione degli occhi persiste, consultare un medico.

2.3 Altri rischi

OSHA HCS 2012 Ai sensi della normativa statunitense (29 CFR 1910.1200 - Standard per la comunicazione dei pericoli), questo prodotto non è considerato pericoloso.

Canada

In ottemperanza a: WHMIS

2.1 Classificazione della sostanza o della miscela

WHMIS Non classificato

2.2 Elementi dell'etichetta

WHMIS Non è richiesta alcuna etichetta.

2.3 Altri rischi

WHMIS In Canada, il prodotto di cui sopra non è considerato pericoloso ai sensi del sistema di informazioni sui materiali pericolosi sul luogo di lavoro (Workplace Hazardous Materials Information System, WHMIS).

2.4 Altre informazioni

Tutti gli altri reagenti, le perline e i costituenti hanno concentrazioni inferiori all'1% nella miscela o non sono considerati pericolosi per le normative sulla comunicazione del pericolo degli USA (29 CFR 1910.1200), le direttive UE per la classificazione e l'etichettatura delle sostanze e delle miscele o per il Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche e delle miscele.

Sezione 3: Composizione/Informazioni sugli ingredienti

3.1 Sostanze

Il materiale non soddisfa i criteri di classificazione come sostanza.

3.2 Miscele

Composizione					
Nome Chimico	**Identificatori**	**%**	**DL50/CL50**	**Classificazioni Secondo Regolamento / Direttiva**	**Commenti**
Guanidina tiocianato	**CAS:**593-84-0 **EINECS:** 209-812-1	10-20%	593 mg/kg	**UE CLP:** Toss. acuta 5, H302, H313, H320 **UN GHS:** Toss. acuta 5 (orale); Irrit. cute 3; Irrit. occhi 2B **OSHA HCS 2012:** Toss. acuta 5 (orale); Irrit. occhi 2B	NDD

Sezione 4: Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Inalazione
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. Portare la persona colpita all'aria aperta. Somministrare ossigeno se la respirazione è difficile. Non usare il metodo bocca-a-bocca se la vittima ha inalato la sostanza; effettuare la respirazione artificiale con l'ausilio di una mascherina con valvola unidirezionale o altro dispositivo medico adeguato. Se la vittima non respira, effettuare la respirazione artificiale.

Cute
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di limitato contatto con la pelle, evitare la dispersione del materiale sulla pelle non interessata. In caso di contatto con la sostanza, sciacquare immediatamente la pelle con acqua corrente per almeno 20 minuti. Rimuovere e isolare gli indumenti contaminati.

Occhi
In normali condizioni di utilizzo raccomandato non si prevede si rendano necessarie misure di pronto soccorso. In caso di contatto con la sostanza, sciacquare immediatamente gli occhi con acqua corrente per almeno 20 minuti. Se l'irritazione degli occhi persiste, consultare un medico.

Ingestione
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di ingestione, sciacquare la bocca con acqua (solamente se l'infortunato è cosciente). NON provocare il vomito. Non usare il metodo bocca-a-bocca se la vittima ha ingerito la sostanza. In caso di ingestione consultare immediatamente il medico.

4.2 Sintomi ed effetti più importanti, acuti e ritardati

Consultare la Sezione 11 - Informazioni tossicologiche.

4.3 Indicazione delle attenzioni mediche immediate e dei trattamenti speciali necessari

Note per il medico
Tutte le cure dovrebbero basarsi sull'osservazione di segni e sintomi di malessere nel paziente. Dovrebbe essere presa in considerazione la possibilità di sovraesposizione a materiali diversi da questo prodotto.

Sezione 5: Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione adeguati	INCENDI DI AMPIE DIMENSIONI: composto chimico secco, CO2, schiumogeno resistente all'alcol o getto d'acqua. INCENDI DI DIMENSIONI RIDOTTE: composto chimico secco, CO2 o getto d'acqua.
Mezzi di estinzione non adeguati	Nessun dato disponibile

5.2 Rischi speciali che scaturiscono dalla sostanza o dalla miscela

Rischi di esplosione e incendi inconsueti	La cartuccia in plastica contenente i reagenti può emettere vapori tossici di ossidi di carbonio, ossidi di zolfo, ossidi di azoto.
Prodotti di combustione pericolosi	Nessun dato disponibile

5.3 Consiglio per i vigili del fuoco

Gli indumenti antincendio strutturali forniscono una protezione limitata SOLO in condizioni di incendio; non sono efficaci in condizioni di fuoriuscite in cui è probabile il contatto diretto con la sostanza.
Indossare abbigliamento protettivo contro gli agenti chimici specificatamente raccomandato dal produttore. Potrebbe fornire limitata o nessuna protezione termica.
Indossare un apparato di respirazione autonomo funzionante a pressione positiva (self-contained breathing apparatus, SCBA).
INCENDI DI DIMENSIONI RIDOTTE: Spostare i contenitori dall'area colpita dall'incendio se non comporta alcun rischio.

Sezione 6: Misure contro il versamento accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure di emergenza

Precauzioni personali	Nel caso in cui si rompa una cartuccia, è possibile applicare queste precauzioni personali. Usare indumenti protettivi adatti. Non camminare sul materiale versato. Toccare i contenitori danneggiati o il materiale versato solo dopo aver indossato l'abbigliamento protettivo adeguato. Ventilare le aree chiuse.
Procedure di emergenza	Non si prevede la necessità di procedure di emergenza se il materiale viene utilizzato in condizioni normali come raccomandato.

6.2 Precauzioni ambientali

Evitare l'ingresso in corsi d'acqua, fognature, seminterrati o aree confinate.

6.3 Metodi e materiali per il contenimento e la pulizia

Misure di contenimento/pulizia	Per piccole fuoriuscite, indossare guanti e assorbire la fuoriuscita con un tovagliolo di carta. Non gettare il materiale fuoriuscito nei tubi di scarico.

6.4 Riferimento ad altre sezioni

Consultare la Sezione 8 - Controlli dell'esposizione / Protezione personale e la Sezione 13 - Considerazioni per lo smaltimento.

Sezione 7: Manipolazione e stoccaggio

7.1 Precauzioni per la manipolazione sicura

Manipolazione Non è necessario nessun trattamento speciale. Nel caso in cui si rompa una cartuccia, evitare il contatto con i reagenti fuoriusciti. Evitare il contatto con gli occhi e con la pelle.

7.2 Condizioni per lo stoccaggio sicuro, incompatibilità eventuali incluse

Stoccaggio Conservare secondo le indicazioni presenti sull'etichetta del prodotto. Tenere lontano dai materiali incompatibili. Conservare sotto chiave. Conservare il recipiente/contenitore ben chiuso in luogo fresco e ben ventilato.

7.3 Usi finali specifici

Consultare la Sezione 1.2 - Usi pertinenti identificati.

Sezione 8: Controlli dell'esposizione / Protezione personale

8.1 Parametri di controllo

	Limiti di Esposizione / Linee Guida			
	Risultato	**ACGIH**	**NIOSH**	**OSHA**
Tiocianato di guanidinio	TWA	Non stabilito	Non stabilito	Non stabilito

8.2 Controlli dell'esposizione

Misure/Controlli tecnici Garantire una ventilazione generale adeguata. I regimi di ventilazione devono essere adeguati alle condizioni. Se applicabile, utilizzare camere di protezione dei processi, impianti di ventilazione locale o altri controlli tecnici per mantenere i livelli di contaminanti aerei al di sotto dei limiti di esposizione raccomandati. Qualora i limiti di esposizione non fossero stati stabiliti, mantenere i contaminanti aerei a un livello accettabile.

Dispositivi di protezione individuale

Respirazione Non si prevede la necessità di attrezzatura respiratoria se il materiale viene utilizzato in condizioni normali come consigliato. Altrimenti, attenersi alle indicazioni del respiratore OSHA disponibili in 29 CFR 1910.134 o nella norma europea EN 149. In caso di superamento dei limiti di esposizione o manifestazione di sintomi, usare un respiratore approvato da NIOSH/MSHA o dalla norma europea EN 149.

Occhi/Volto Indossare occhiali protettivi per sostanze chimiche.

Pelle/Corpo Indossare indumenti protettivi.

Controlli dell'esposizione ambientale Seguire le migliori pratiche per la gestione del sito e per lo smaltimento dei rifiuti.

Legenda delle abbreviazioni
OSHA = Occupational Safety and Health Administration (Agenzia per la salute e la sicurezza sul lavoro)
TWA = Time-Weighted Averages (Medie pesate nel tempo) basate su esposizioni da 8 ore/giorno, 40 ore/settimana

Sezione 9: Proprietà chimico-fisiche

9.1 Informazioni sulle proprietà chimico-fisiche

Descrizione del materiale			
Forma fisica	Liquido	Colore	Incolore
Odore	Inodore	Soglia di odore	Dati mancanti
Proprietà generali			
Punto di ebollizione	100 °C (212 °F)	Punto di fusione/Punto di congelamento	0 °C (32 °F)
Temperatura di decomposizione	Dati mancanti	pH	da 3,3 a 8,8
Gravità specifica/densità relativa	= 1 Acqua=1	Solubilità in acqua	Solubile al 100%
Viscosità	Dati mancanti	Proprietà esplosive	Dati mancanti
Proprietà ossidanti:	Dati mancanti		
Volatilità			
Pressione di vapore	Minima	Densità del vapore	Dati mancanti
Tasso di evaporazione	Minimo		
Infiammabilità			
Punto di infiammabilità	Dati mancanti	UEL	Dati mancanti
LEL	Dati mancanti	Autoaccensione	Dati mancanti
Infiammabilità (solido, gas):	Dati mancanti		
Ambientali			
Coefficiente di ripartizione ottanolo-acqua	Dati mancanti		

9.2 Altre informazioni

Non sono state osservate altre proprietà chimico-fisiche.

Sezione 10: Stabilità e reattività

10.1 Reattività

Nessuna reazione pericolosa nota nelle normali condizioni di utilizzo.

10.2 Stabilità chimica

Stabile

10.3 Possibilità di reazioni pericolose

Non si verificherà polimerizzazione pericolosa.

10.4 Condizioni da evitare

Materiali incompatibili. La combustione della cartuccia in plastica contenente i reagenti può liberare sottoprodotti tossici.

10.5 Materiali incompatibili

Acidi.

10.6 Prodotti di decomposizione pericolosi

La combustione della cartuccia in plastica contenente i reagenti può liberare sottoprodotti tossici.

Sezione 11: Informazioni tossicologiche

11.1 Informazioni sugli effetti tossicologici

Componenti		
Tiocianato di guanidinio	593-84-0	**Tossicità acuta:** Intraperitoneale-Topo DL50 • 593 mg/kg

Proprietà GHS	Classificazione
Tossicità acuta	**EU/CLP**•Dati mancanti **UN GHS**•Tossicità acuta – Orale 5 **OSHA HCS 2012**•Dati mancanti
Corrosione/Irritazione cutanea	**EU/CLP**•Dati mancanti **UN GHS**• Lieve irritazione cutanea 3 **OSHA HCS 2012**•Dati mancanti
Grave irritazione/danno oculare	**EU/CLP**•Dati mancanti **UN GHS**•Lieve irritazione oculare 2B **OSHA HCS 2012**•Lieve irritazione oculare 2B
Sensibilizzazione cutanea	**EU/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Sensibilizzazione respiratoria	**EU/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Cancerogenicità	**EU/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Mutagenesi delle cellule embrionali	**EU/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Tossicità per la riproduzione	**EU/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-SE	**EU/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti

Potenziali effetti sulla salute

Inalazione
Acuto (immediato) Può causare irritazione.
Cronico (ritardato) Nessun dato disponibile
Cute
Acuto (immediato) Provoca lieve irritazione cutanea.
Cronico (ritardato) Nessun dato disponibile
Occhi
Acuto (immediato) Provoca irritazione oculare.
Cronico (ritardato) Nessun dato disponibile
Ingestione
Acuto (immediato) Può essere nocivo se ingerito.
Cronico (ritardato) Nessun dato disponibile

Legenda delle abbreviazioni
DL = dose letale

Sezione 12: Informazioni ecologiche

12.1 Tossicità

CL50 (guppy): 89,1 mg/l a 96 h

12.2 Persistenza e degradabilità

Dati materiale mancanti.

12.3 Potenziale di bioaccumulo

Dati materiale mancanti.

12.4 Mobilità nel suolo

Dati materiale mancanti.

12.5 Risultati della valutazione PBT e vPvB

Non sono state condotte valutazioni PBT e vPvB.

12.6 Altri effetti avversi

Non sono stati trovati studi.

Sezione 13: Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti del prodotto	Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.
Rifiuti di imballaggio	Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

13.2 Altre informazioni

I campioni biologici di analisi, i dispositivi di trasferimento e le cartucce usate devono essere trattati come potenziali veicoli di agenti infettivi adottando le precauzioni standard. Attenersi alle procedure di smaltimento dei rifiuti ambientali della propria struttura sanitaria per il corretto smaltimento delle cartucce usate e dei reagenti non utilizzati. Questi materiali potrebbero essere considerati rifiuti chimici pericolosi per il cui smaltimento sarà necessario attenersi a specifiche procedure nazionali o regionali. Se i regolamenti nazionali o regionali non forniscono istruzioni chiare sul corretto smaltimento, i campioni biologici di analisi e le cartucce usate devono essere smaltiti in base alle linee guida dell'OMS (Organizzazione mondiale della sanità) sulla manipolazione e lo smaltimento dei rifiuti medici.

Sezione 14: Informazioni sul trasporto

	14.1 Numero ONU	14.2 Nome di spedizione corretto ONU	14.3 Classi di pericolosità per il trasporto	14.4 Gruppo di imballaggio	14.5 Pericoli ambientali
DOT	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile
TDG	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile
IMO/IMDG	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile
IATA/ICAO	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile

14.6 Precauzioni speciali per l'utilizzatore

Nessuna specificata.

14.7 Trasporto alla rinfusa in conformità all'Allegato II di MARPOL 73/78 e al codice IBC

Non pertinente.

Sezione 15: Informazioni regolatorie

15.1 Normative/legislazione in materia di ambiente, salute e sicurezza specifiche per la sostanza o la miscela

Classificazioni dei rischi SARA Acuta

Inventario						
Componente	**CAS**	**Canada DSL**	**Canada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Tiocianato di guanidinio	593-84-0	Sì	No	Sì	No	Sì

Canada

Lavoro

Canada - WHMIS - Classificazione delle sostanze
•Tiocianato di guanidinio 593-84-0 Non elencato

Canada - WHMIS - Elenco degli ingredienti
•Tiocianato di guanidinio 593-84-0 Non elencato

Ambiente

Canada - CEPA - Elenco sostanze prioritarie
•Tiocianato di guanidinio 593-84-0 Non elencato

Stati Uniti

Lavoro

USA - OSHA - Gestione dei processi di sicurezza - Sostanze chimiche estremamente pericolose
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - OSHA - Prodotti chimici specificamente regolati
•Tiocianato di guanidinio 593-84-0 Non elencato

Ambiente

USA - CAA (Clean Air Act) - 1990 Inquinanti pericolosi per l'aria
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - CERCLA/SARA - Sostanze pericolose e quantità riportabili
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - CERCLA/SARA - Radionuclidi e quantità riportabili
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose EPCRA RQ
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose TPQ
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - CERCLA/SARA - Sezione 313 - Rapporto sulle emissioni
•Tiocianato di guanidinio 593-84-0 Non elencato

USA - CERCLA/SARA - Sezione 313 - Certificazione chimica PBT
•Tiocianato di guanidinio 593-84-0 Non elencato

Stati Uniti - California

Ambiente

USA - California – Proposta 65 - Elenco sostanze cancerogene		
•Tiocianato di guanidinio	593-84-0	Non elencato
USA - California – Proposta 65 - Tossicità evolutiva		
•Tiocianato di guanidinio	593-84-0	*Non elencato*
USA - California - Proposta 65 - MADL (Maximum Allowable Dose Levels, livelli di dose massimi consentiti)		
•Tiocianato di guanidinio	593-84-0	Non elencato
USA - California - Proposta 65 - NSRL (No Significant Risk Levels, nessun livello di rischio significativo)		
•Tiocianato di guanidinio	593-84-0	Non elencato
USA - California - Proposta 65 - Tossicità sulla riproduzione - Femminile		
•Tiocianato di guanidinio	593-84-0	Non elencato
USA - California - Proposta 65 - Tossicità sulla riproduzione - Maschile		
•Tiocianato di guanidinio	593-84-0	Non elencato

15.2 Valutazione della sicurezza chimica

Non è stata eseguita alcuna valutazione della sicurezza chimica.

Sezione 16: Altre informazioni

Frasi pertinenti (codice e testo completo)

H302 – Nocivo se ingerito
H313 – Può essere nocivo per contatto con la pelle
H320 – Provoca irritazione oculare

Esclusione/Dichiarazione di responsabilità

Le suddette informazioni si basano su dati a nostra disposizione e ritenuti corretti. Poiché le informazioni possono essere applicate in condizioni che vanno oltre il nostro controllo e che potremmo non conoscere bene, non ci assumiamo nessuna responsabilità per i risultati derivanti dall'uso che ne viene fatto, e tutte le persone che ne usufruiranno devono stabilire gli effetti, le proprietà, le protezioni e lo smaltimento riguardanti ogni singola situazione. Nessuna rappresentazione, garanzia o assicurazione, esplicita o implicita (comprese una garanzia di idoneità o commerciabilità per un particolare scopo), viene fatta per quanto riguarda i materiali, la precisione delle informazioni fornite, i risultati ottenibili dall'uso che ne viene fatto, o i pericoli connessi con l'uso del materiale. L'uso e la manipolazione del materiale devono essere eseguiti con attenzione. Le suddette informazioni sono fornite in buona fede e con la convinzione che siano esatte. A partire dalla data di emissione, vengono fornite tutte le informazioni a disposizione relativamente al trattamento prevedibile del materiale. Tuttavia, in caso di un incidente avverso relativo al prodotto, questa scheda dati di sicurezza non è, e non intende essere, il surrogato della consultazione con personale opportunamente addestrato.

Legenda delle abbreviazioni
NDD = Nessun dato disponibile

Veiligheidsinformatieblad
Ingangsdatum: Januari 2021
Vervangt datum: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Rubriek 1: Identificatie van de stof of het preparaat en van de onderneming

1.1 Identificatie product

Productnaam	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Productcode	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Relevant geïdentificeerd gebruik van het preparaat/mengsel en ontraden gebruik

Relevant geïdentificeerd gebruik	Laboratoriumgebruik

1.3 Gegevens van de leverancier van het veiligheidsinformatieblad

Fabrikant	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Verenigde Staten www.cepheid.com VS: techsupport@cepheid.com
Telefoon (algemeen)	+1 (888) 838-3222 - VS optie 2
Telefoon (algemeen)	+1 (408) 541-4191 - buiten de VS
Leverancier	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Zweden www.cepheidinternational.com EU: support@cepheideurope.com
Telefoon (algemeen)	+33 563 825 319
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australië www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
Telefoon (Australië)	1800 107 884

1.4 Noodtelefoonnummer

Fabrikant	+1 (800) 535-5053 - INFOTRAC - 24-uurs noodlijn
Fabrikant	+1 (352) 323-3500 - buiten de VS

Rubriek 2: Identificatie van de gevaren

EU/EEC
Volgens: Verordening (EG) nr. 1272/2008 (CLP)/REACH 1907/2006 [geamendeerd door 453/2010]

2.1 Indeling van de stof of het mengsel

CLP

Het volgende VIB is voor het gemengde eindproduct zoals in het laboratorium gebruikt. Het product bevat korrels en reagentia in de patroon of in externe containers. Uitzonderingen voor het vrijgeven van enige componentinformatie zijn volgens CLP-artikel 1(5)(d) en 29 CFR 1910.1200(g)(2)(i)(C)(1) en (2).
Niet geclassificeerd

2.2 Etiketteringselementen

CLP

Gevarenaanduidingen Geen etiketteringselementen vereist

2.3 Overige gevaren

CLP

Onder Verordening (EG) nr. 1272/2008 CLP wordt dit materiaal niet als gevaarlijk beschouwd.

UN GHS (etikettering inhoud gebruikt op producten)
Volgens: Wereldwijd geharmoniseerd systeem voor de indeling en etikettering van chemische stoffen (Globally Harmonized System of classification and labelling of chemicals (GHS)) van de Verenigde Naties

2.1 Indeling van de stof of het mengsel

UN GHS

Acute orale toxiciteit 5
Mild huidirriterend 3
Mild oogirriterend 2B

2.2 Etiketteringselementen

UN GHS

WAARSCHUWING

Gevarenaanduidingen

Schadelijk bij inslikken
Mogelijk schadelijk bij contact met de huid
Veroorzaakt oogirritatie

Voorzorgsmaatregelen

Preventie Na het werken met dit product handen grondig wassen.

Antwoord Bij huidirritatie: Een arts raadplegen.
BIJ CONTACT MET DE OGEN: Voorzichtig afspoelen met water gedurende een aantal minuten. Contactlenzen verwijderen, indien mogelijk. Blijven spoelen.
Bij aanhoudende oogirritatie: Een arts raadplegen.
Bij onwel voelen een VERGIFTIGINGENCENTRUM (NL) of ANTIGIFCENTRUM (BE) of een arts raadplegen.

2.3 Overige gevaren

UN GHS

Onder het wereldwijd geharmoniseerd systeem voor de indeling en etikettering van chemische stoffen (Globally Harmonized System of classification and labelling of chemicals (GHS)) van de Verenigde Naties wordt dit product als gevaarlijk beschouwd.

Verenigde Staten (VS)
Volgens: OSHA 29 CFR 1910.1200 HCS

2.1 Indeling van de stof of het mengsel

OSHA HCS 2012

Mild oogirriterend 2B

2.2 Etiketteringselementen

OSHA HCS 2012

Gevarenaanduidingen

Schadelijk bij inslikken
Schadelijk bij contact met de huid
Veroorzaakt oogirritatie

Voorzorgsmaatregelen

Preventie

Na het werken met dit product handen grondig wassen.

Antwoord

BIJ CONTACT MET DE OGEN: Voorzichtig afspoelen met water gedurende een aantal minuten. Contactlenzen verwijderen, indien mogelijk. Blijven spoelen.
Bij aanhoudende oogirritatie: Een arts raadplegen.

2.3 Overige gevaren

OSHA HCS 2012

Onder regelgeving van de VS (29 CFR 1910.1200 - Hazard Communication Standard) wordt dit product niet als gevaarlijk beschouwd.

Canada
Volgens: WHMIS

2.1 Indeling van de stof of het mengsel

WHMIS

Niet geclassificeerd

2.2 Etiketteringselementen

WHMIS

Geen etiketteringselementen vereist.

2.3 Overige gevaren

WHMIS

In Canada wordt het hierboven genoemde product niet als gevaarlijk beschouwd onder het Workplace Hazardous Materials Information System (WHMIS).

2.4 Overige informatie

Alle andere reagentia, korrels en andere bestanddelen hebben een concentratie van minder dan 1% in het mengsel of worden niet als gevaarlijk beschouwd onder de gevarencommunicatieregelgeving van de VS (29 CFR 1910.1200), EU-richtlijnen voor classificatie en etikettering van stoffen of mengsels of het wereldwijd geharmoniseerd systeem voor de indeling en etikettering van stoffen of mengsels.

Rubriek 3: Samenstelling en informatie over de bestanddelen

3.1 Stoffen

Het materiaal voldoet niet aan de criteria voor een stof.

3.2 Mengsels

Samenstelling					
Chemische naam	**Identificatoren**	**%**	**LD50/LC50**	**Classificaties volgens verordening/richtlijn**	**Opmerkingen**
Guanidine thiocyanaat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**EU CLP:** Acute toxiciteit 5, H302, H313, H320 **UN GHS:** Acute toxiciteit 5 (Orl); Huidirriterend 3; Oogirriterend 2B **OSHA HCS 2012:** Acute toxiciteit 5 (Orl); Oogirriterend 2B	GGB

Rubriek 4: EHBO-maatregelen

4.1 Beschrijving van eerstehulpmaatregelen

Inhalatie Naar verwachting is geen eerste hulp nodig als het materiaal onder normale omstandigheden en zoals aanbevolen wordt gebruikt. Verplaats het slachtoffer naar de frisse lucht. Bij moeilijk ademen zuurstof toedienen. Gebruik geen mond-op-mondmethode indien het slachtoffer de stof heeft ingeademd. Beadem kunstmatig met een beademingsmasker met eenrichtingsventiel of een ander toepasselijk medisch apparaat. Beadem kunstmatig indien het slachtoffer niet ademt.

Huid Naar verwachting is geen eerste hulp nodig als het materiaal onder normale omstandigheden en zoals aanbevolen wordt gebruikt. Voor gering huidcontact voorkomen dat het materiaal naar onaangetaste huid wordt verspreid. Bij contact met de stof de huid direct minstens 20 minuten onder stromend water spoelen. Verwijder en isoleer besmette kleding.

Oog Naar verwachting is geen eerste hulp nodig als het materiaal onder normale omstandigheden en zoals aanbevolen wordt gebruikt. Bij contact met de stof de ogen direct minstens 20 minuten onder stromend water spoelen. Bij aanhoudende oogirritatie: Een arts raadplegen.

Inslikken Naar verwachting is geen eerste hulp nodig als het materiaal onder normale omstandigheden en zoals aanbevolen wordt gebruikt. Bij inslikken de mond spoelen met water (alleen als de persoon bij bewustzijn is). GEEN braken opwekken. Gebruik geen mond-op-mondmethode indien het slachtoffer de stof heeft ingeslikt. Zoek bij inslikken onmiddelijk medische hulp.

4.2 Belangrijkste symptomen en effecten, zowel acuut als later optredend

Raadpleeg rubriek 11, Toxicologische informatie.

4.3 Indicatie van alle vereiste directe medische zorg en speciale behandelingen

Opmerkingen voor de arts Alle behandelingen moeten worden gebaseerd op de geobserveerde tekenen en symptomen van ongerief van de patiënt. Rekening moet worden gehouden met de mogelijkheid dat te hoge blootstelling aan andere materialen dan dit product kan zijn opgestreden.

Rubriek 5: Brandbestrijdingsmaatregelen

5.1 Blusmiddelen

Geschikte blusmiddelen	GROTE BRANDEN: Droog chemisch, CO2, alcoholbestendig schuim of sproeiwater. KLEINE BRANDEN: Droog chemisch, CO2 of sproeiwater.
Ongeschikte blusmiddelen	Geen gegevens beschikbaar

5.2 Specifieke gevaren van de stof of het mengsel

Buitengewone brand- en explosiegevaren	De plastic patroon met reagentia kan giftige dampen afgeven met koolstofoxiden, zwavenoxiden en stikstofoxiden.
Gevaarlijke verbrandingsproducten	Geen gegevens beschikbaar

5.3 Advies voor brandweer

De structurele beschermende kleding van de brandweer biedt ALLEEN bij brand beperkte bescherming. De kleding is niet effectief bij lekkages waarbij direct contact met de stof mogelijk is.
Draag de tegen chemicaliën beschermende kleding die specifiek door de fabrikant wordt aangeraden. Deze kleding kan weinig tot geen bescherming tegen hitte bieden.
Draag zelfstandige ademhalingsapparatuur met positieve druk.
KLEINE BRANDEN: Verwijder containers uit het gebied van de brand als dit zonder risico mogelijk is.

Rubriek 6: Maatregelen bij accidenteel vrijkomen

6.1 Persoonlijke voorzorgsmaatregelen, beschermende apparatuur en noodprocedures

Persoonlijke voorzorgsmaatregelen	Als een patroon gebroken is, zijn deze persoonlijke voorzorgsmaatregelen van toepassing. Draag de juiste beschermende kleding. Loop niet door vrijgekomen materiaal. Raak geen beschadigde containers of vrijgekomen materiaal aan, tenzij u toepasselijke beschermende kleding draagt. Ventileer afgesloten ruimten.
Noodprocedures	Naar verwachting zijn geen noodprocedures nodig als het materiaal onder normale omstandigheden en zoals aanbevolen wordt gebruikt.

6.2 Voorzorgsmaatregelen voor het milieu

Voorkom vrijkomen in waterwegen, riolering, kelders of besloten gebieden.

6.3 Methoden en materialen voor inperking en opruimen

Maatregelen voor inperking en opruimen	Draag bij kleine lekkages handschoenen en absorbeer weggelekt materiaal met papieren doekjes. Laat weggelekt materiaal niet via afvoeren weglopen.

6.4 Verwijzing naar andere rubrieken

Zie rubriek 8, Maatregelen ter beheersing van blootstelling/persoonlijke bescherming en rubriek 13, Instructies voor verwijdering.

Rubriek 7: Opslag en hantering

7.1 Voorzorgsmaatregelen voor veilige hantering

Hantering Geen speciale hantering vereist. Vermijd indien patroon gebroken is contact met vrijgekomen reagentia. Vermijd contact met huid en ogen.

7.2 Voorwaarden voor veilige opslag, inclusief incompatibiliteiten

Opslag Opslaan volgens productetikettering. Verwijderd houden van incompatibele materialen. Achter slot bewaren. Bewaar container/verpakking goed gesloten op een koele, goed geventileerde plaats.

7.3 Specifiek eindgebruik

Zie rubriek 1.2, Relevant geïdentificeerd gebruik.

Rubriek 8: Maatregelen ter beheersing van blootstelling/persoonlijke bescherming

8.1 Beheersingsparameters

	Blootstellingsgrenzen en -richtlijnen			
	Resultaat	**ACGIH**	**NIOSH**	**OSHA**
Guanidine thiocyanaat	TWA	Niet vastgesteld	Niet vastgesteld	Niet vastgesteld

8.2 Maatregelen ter beheersing van blootstelling

Technische maatregelen Er moet goede algemene ventilatie worden gebruikt. De ventilatiesnelheid moet aan de omstandigheden worden aangepast. Gebruik indien van toepassing zuurkasten, plaatselijke ventilatie met afzuiging of andere technische maatregelen voor het onder de vereiste blootstellingslimieten houden van niveaus in de lucht. Indien geen blootstellingslimieten zijn vastgesteld, moeten niveaus in de lucht op een acceptabel niveau worden gehouden.

Persoonlijke beschermingsmiddelen

Ademhaling Naar verwachting is geen ademhalingsapparatuur nodig als het materiaal onder normale omstandigheden en zoals aanbevolen wordt gebruikt. Volg anders de OSHA-regelgeving voor ademhalingsapparatuur in 29 CFR 1910.134 of de Europese norm EN 149. Gebruik een NIOSH/MSHA- of onder de Europese norm EN 149 goedgekeurd ademhalingstoestel als de blootstellingslimieten worden overschreden of symptomen worden ervaren.

Ogen/gezicht Draag een veiligheidsbril tegen opspattende chemische stoffen.

Huid/lichaam Draag beschermende kleding

Beheersing van milieublootstelling Volg de beste werkwijze voor locatiebeheer en afvoer van afval.

Uitleg van afkortingen
OSHA = Occupational Safety and Health Administration (arbeidsomstandighedenautoriteit VS)
TWA = Time-Weighted Averages: tijdgewogen gemiddelden gebaseerd op blootstelling gedurende 8 uur per dag, 40 uur per week

Rubriek 9: Fysische en chemische eigenschappen

9.1 Informatie over fysische en chemische eigenschappen

Materiaalbeschrijving			
Fysische vorm	Vloeistof	Kleur	Kleurloos
Geur	Geurloos	Geurdrempel	Gegevens ontbreken
Algemene eigenschappen			
Kookpunt	100 °C (212 °F)	Smeltpunt/vriespunt	0 °C (32 °F)
Ontledingstemperatuur	Gegevens ontbreken	pH	3,3, tot 8,8
Soortelijk gewicht/relatieve dichtheid	= 1 Water=1	Wateroplosbaarheid	100% oplosbaar
Viscositeit	Gegevens ontbreken	Ontploffingseigenschappen	Gegevens ontbreken
Oxiderende eigenschappen:	Gegevens ontbreken		
Vluchtigheid			
Dampdruk	Minimaal	Dampdichtheid	Gegevens ontbreken
Verdampingssnelheid	Minimaal		
Brandbaarheid			
Ontbrandingspunt	Gegevens ontbreken	UEL	Gegevens ontbreken
LEL	Gegevens ontbreken	Zelfontbranding	Gegevens ontbreken
Brandbaarheid (vaste stof, gas)	Gegevens ontbreken		
Milieu			
Verdelingscoëfficiënt octanol/water	Gegevens ontbreken		

9.2 Overige informatie

Geen aanvullende fysische en chemische parameters genoemd.

Rubriek 10: Stabiliteit en reactiviteit

10.1 Reactiviteit

Geen gevaarlijke reactie bekend onder normale gebruiksomstandigheden.

10.2 Chemische stabiliteit

Stabiel

10.3 Mogelijke gevaarlijke reacties

Gevaarlijk polymerisatie treedt niet op.

10.4 Te vermijden omstandigheden

Incompatibele materialen. Verbranding van plastic patronen met reagentia kan giftige bijproducten laten vrijkomen.

10.5 Incompatibele materialen

Zuren.

10.6 Gevaarlijke ontledingsproducten

Verbranding van plastic patronen met reagentia kan giftige bijproducten laten vrijkomen.

Rubriek 11: Toxicologische informatie

11.1 Informatie over toxicologische effecten

Bestanddelen		
Guanidine thiocyanaat	593-84-0	**Acute toxiciteit:** Intraperitoneaal: LD50 muis • 593 mg/kg

GHS-kenmerken	Classificatie
Acute toxiciteit	**EU/CLP**•Gegevens ontbreken **UN GHS**•Acute toxiciteit: oraal 5 **OSHA HCS 2012**•Gegevens ontbreken
Huidcorrosie/-irritatie	**EU/CLP**•Gegevens ontbreken **UN GHS**•Milde huidirritatie 3 **OSHA HCS 2012**•Gegevens ontbreken
Ernstige oogschade/irritatie	**EU/CLP**•Gegevens ontbreken **UN GHS**•Milde oogirritatie 2B **OSHA HCS 2012**•Milde oogirritatie 2B
Sensibilisatie van de huid	**EU/CLP**•Gegevens ontbreken **UN GHS**•Gegevens ontbreken **OSHA HCS 2012**•Gegevens ontbreken
Sensibilisatie van de luchtwegen	**EU/CLP**•Gegevens ontbreken **UN GHS**•Gegevens ontbreken **OSHA HCS 2012**•Gegevens ontbreken
Carcinogeniciteit	**EU/CLP**•Gegevens ontbreken **UN GHS**•Gegevens ontbreken **OSHA HCS 2012**•Gegevens ontbreken
Mutageniteit voor kiemcellen	**EU/CLP**•Gegevens ontbreken **UN GHS**•Gegevens ontbreken **OSHA HCS 2012**•Gegevens ontbreken
Giftigheid voor de voortplanting	**EU/CLP**•Gegevens ontbreken **UN GHS**•Gegevens ontbreken **OSHA HCS 2012**•Gegevens ontbreken
STOT-SE	**EU/CLP**•Gegevens ontbreken **UN GHS**•Gegevens ontbreken **OSHA HCS 2012**•Gegevens ontbreken

Potentiële effecten op de gezondheid

Inhalatie
Acuut (direct) Kan irritatie veroorzaken.
Chronisch (vertraagd) Geen gegevens beschikbaar.

Huid
Acuut (direct) Veroorzaakt milde huidirritatie.
Chronisch (vertraagd) Geen gegevens beschikbaar.

Oog
Acuut (direct) Veroorzaakt oogirritatie.
Chronisch (vertraagd) Geen gegevens beschikbaar.

Inslikken
Acuut (direct) Kan schadelijk zijn bij inslikken.
Chronisch (vertraagd) Geen gegevens beschikbaar.

Uitleg van afkortingen
LD = Lethal Dose (dodelijke dosis)

Rubriek 12: Ecologische informatie

12.1 Toxiciteit

LC50 (guppy): 89,1 mg/l bij 96 uur

12.2 Persistentie en afbreekbaarheid

Gegevens materiaal ontbreken.

12.3 Mogelijke bioaccumulatie

Gegevens materiaal ontbreken.

12.4 Mobiliteit in de bodem

Gegevens materiaal ontbreken.

12.5 Resultaten van PBT- en zPzB-beoordeling

Geen PBT- en zPzB-beoordeling uitgevoerd.

12.6 Andere schadelijke effecten

Geen onderzoeken gevonden.

Rubriek 13: Instructies voor verwijdering

13.1 Afvalverwerkingsmethoden

Productafval	Voer de inhoud en/of container af volgens de plaatselijke, regionale, nationale en/of internationale wet- en regelgeving.
Verpakkingsafval	Voer de inhoud en/of container af volgens de plaatselijke, regionale, nationale en/of internationale wet- en regelgeving.

13.2 Overige informatie

Biologische monsters, transferhulpmiddelen en gebruikte patronen moeten worden beschouwd alsof ze in staat zijn infectieuze agentia over te dragen en vereisen standaardvoorzorgsmaatregelen. Volg de procedures van uw instelling inzake milieuafval voor de juiste afvoer van gebruikte patronen en ongebruikte reagentia. Deze materialen kunnen kenmerken van chemisch gevaarlijk afval vertonen dat in uw land of regio op een specifieke wijze moet worden afgevoerd. Als nationale of regionale voorschriften geen duidelijke aanwijzingen geven voor de juiste afvoer, moeten biologische monsters en gebruikte patronen worden afgevoerd volgens de richtlijnen van de Wereldgezondheidsorganisatie (World Health Organization, WHO) inzake het hanteren en afvoeren van medisch afval.

Rubriek 14: Vervoersinformatie

	14.1 VN-nummer	14.2 Juiste ladingnaam overeenkomstig de modelreglementen van de VN	14.3 Transport-gevarenklasse(n)	14.4 Verpakkings-groep	14.5 Milieugevaren
DOT	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet van toepassing
TDG	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet van toepassing
IMO/IMDG	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet van toepassing
IATA/ICAO	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet gereguleerd	Niet van toepassing

14.6 Speciale voorzorgsmaatregelen voor gebruiker

Geen gespecificeerd.

14.7 Vervoer in bulk overeenkomstig bijlage II bij MARPOL 73/78 en de IBC-code

Niet relevant.

Rubriek 15: Wettelijk verplichte informatie

15.1 Specifieke veiligheids-, gezondheids- en milieureglementen en -wetgeving voor de stof of het mengsel

SARA-gevarenclassificaties Acuut

Voorraad						
Bestanddeel	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidine thiocyanaat	593-84-0	Ja	Nee	Ja	Nee	Ja

Canada

Arbeid

Canada - WHMIS - Classifications of Substances

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

Canada - WHMIS - Ingredient Disclosure List

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

Milieu

Canada - CEPA - Priority Substances List

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

Verenigde Staten

Arbeid

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - OSHA - Specifically Regulated Chemicals

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

Milieu

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

•Guanidine thiocyanaat	593-84-0	Niet opgenomen

Verenigde Staten - Californië

Milieu

U.S. - California - Proposition 65 - Carcinogens List		
•Guanidine thiocyanaat	593-84-0	Niet opgenomen
U.S. - California - Proposition 65 - Developmental Toxicity		
•Guanidine thiocyanaat	593-84-0	*Niet opgenomen*
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Guanidine thiocyanaat	593-84-0	Niet opgenomen
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Guanidine thiocyanaat	593-84-0	Niet opgenomen
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Guanidine thiocyanaat	593-84-0	Niet opgenomen
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Guanidine thiocyanaat	593-84-0	Niet opgenomen

15.2 Chemische veiligheidsbeoordeling

Er is geen chemische veiligheidsbeoordeling uitgevoerd.

Rubriek 16: Overige informatie

Relevante zinnen (code en volledige tekst)

H302: Schadelijk bij inslikken.
H313: Schadelijk bij contact met de huid.
H320: Veroorzaakt oogirritatie.

Disclaimer/ verklaring van aansprakelijkheid

De bovenstaande informatie is gebaseerd op de voor ons beschikbare gegevens en wordt als correct beschouwd. Omdat de informatie kan worden toegepast onder omstandigheden die buiten onze controle liggen en waar wij wellicht niet bekend zijn, aanvaarden wij geen enkele aansprakelijkheid voor het resultaat van het gebruik ervan en moet iedereen die deze ontvangt een eigen afweging maken over de effecten, kenmerken, bescherming en afvoer met betrekking tot de specifieke omstandigheden. Geen verklaring, garantie of waarborg, expliciet of impliciet (waaronder garantie van geschikheid voor verhandelbaarheid voor een bepaald doel) wordt gedaan ten aanzien van de materialen, de nauwkeurigheid van deze informatie, de te behalen resultaten uit het gebruik hiervan of de gevaren verbonden aan het gebruik van het materiaal. Het materiaal moet voorzichtig worden gehanteerd en gebruikt. De bovenstaande informatie wordt in goed vertrouwen geleverd en wordt als correct beschouwd. Per de datum van uitgifte bieden we alle informatie relevant voor voorzienbare hantering van het materiaal. In geval van een nadelig incident met betrekking tot dit product is dit veiligheidsinformatieblad niet, en niet bedoeld te zijn, een vervanging voor het raadplegen van toepasselijk opgeleid personeel.

Uitleg van afkortingen
GGB = geen gegevens beschikbaar

Karta charakterystyki substancji
Data wejścia w życie: Styczeń 2021 r.
Zastępuje wersję z: Wrzesień 2020 r.

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Sekcja 1: Identyfikacja substancji/mieszaniny i identyfikacja spółki/przedsiębiorstwa

1.1 Identyfikator produktu

Nazwa produktu	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Kod produktu	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Istotne zidentyfikowane zastosowania substancji lub mieszaniny oraz zastosowania odradzane

Istotne zidentyfikowane zastosowania	Zastosowania laboratoryjne

1.3 Dane dotyczące dostawcy karty charakterystyki

Producent	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Stany Zjednoczone www.cepheid.com USA: techsupport@cepheid.com
Numer telefonu (informacje ogólne)	1 (888) 838-3222 — USA, opcja nr 2
Numer telefonu (informacje ogólne)	1 (408) 541-4191 — spoza USA
Dostawca	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Szwecja www.cepheidinternational.com EU: support@cepheideurope.com
Numer telefonu (informacje ogólne)	+33 563 825 319
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
Telefon (Australia)	1800 107 884

1.4 Numer telefonu alarmowego

Producent	1 (800) 535-5053 — INFOTRAC — sytuacje awaryjne całodobowo
Producent	1 (352) 323-3500 — spoza USA

Sekcja 2: Identyfikacja zagrożeń

EU/EEC

Zgodnie z: Rozporządzenie (WE) nr 1272/2008 (CLP)/REACH 1907/2006 [z późniejszymi zmianami wprowadzonymi przez 453/2010]

2.1 Klasyfikacja substancji lub mieszaniny

CLP

Niniejsza karta charakterystyki substancji dotyczy używanego w laboratorium końcowego, gotowego produktu będącego mieszaniną. Ten produkt zawiera kulki i odczynniki w kartridżach albo w pojemnikach poza instrumentem. Zwolnienia z ujawniania informacji na temat niektórych składników zgodnie z art. 1(5)(d) i 29 rozporządzenia CLP i 1910.1200(g)(2)(i)(C)(1) i (2) kodeksu CFR.
Nie sklasyfikowano

2.2 Elementy oznakowania

CLP

Zwroty dotyczące zagrożeń

Nie są wymagane żadne elementy etykiety

2.3 Inne zagrożenia

CLP

Ten materiał nie jest uznawany za niebezpieczny zgodnie z Rozporządzeniem (WE) nr 1272/2008 (CLP).

GHS ONZ (zawartość etykiety używanej na produktach)

Zgodnie z: Globalnie Zharmonizowanym Systemem Klasyfikacji i Oznakowania Chemikaliów (GHS) ONZ

2.1 Klasyfikacja substancji lub mieszaniny

GHS ONZ

Toksyczność ostra, doustnie 5
Łagodne podrażnienie skóry 3
Łagodne podrażnienie oczu 2B

2.2 Elementy oznakowania

GHS ONZ

OSTRZEŻENIE

Zwroty dotyczące zagrożeń

Szkodliwy w przypadku połknięcia
Może działać szkodliwie w kontakcie ze skórą
Powoduje podrażnienie oczu

Zwroty wskazujące środki ostrożności

Zapobieganie Dokładnie umyć ręce po użyciu.

Odpowiedź W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.

2.3 Inne zagrożenia

GHS ONZ Ten produkt jest uznawany za niebezpieczny zgodnie z Globalnie Zharmonizowanym Systemem Klasyfikacji i Oznakowania Chemikaliów (GHS) ONZ.

Stany Zjednoczone (USA)
Zgodnie z: OSHA 29 CFR 1910.1200 HCS

2.1 Klasyfikacja substancji lub mieszaniny

OSHA HCS 2012 Łagodne podrażnienie oczu 2B

2.2 Elementy oznakowania

OSHA HCS 2012

Zwroty dotyczące zagrożeń
Działa szkodliwie po połknięciu
Może działać szkodliwie w kontakcie ze skórą
Powoduje podrażnienie oczu

Zwroty wskazujące środki ostrożności

Zapobieganie Dokładnie umyć ręce po użyciu.

Odpowiedź W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

2.3 Inne zagrożenia

OSHA HCS 2012 Ten produkt nie jest uznawany za niebezpieczny zgodnie z przepisami prawa Stanów Zjednoczonych (29 CFR 1910.1200 — Hazard Communication Standard, Norma dotycząca przekazywania informacji o zagrożeniach).

Kanada
Zgodnie z: WHMIS

2.1 Klasyfikacja substancji lub mieszaniny

WHMIS Nie sklasyfikowano

2.2 Elementy oznakowania

WHMIS Nie są wymagane żadne elementy etykiety.

2.3 Inne zagrożenia

WHMIS W Kanadzie produkt wymieniony powyżej nie jest uznawany za niebezpieczny zgodnie z systemem WHMIS (Workplace Hazardous Materials Information System, system informacji o produktach niebezpiecznych w miejscu pracy).

2.4 Inne informacje

Wszystkie inne odczynniki, kulki oraz inne składniki występują w mieszaninie w stężeniach mniejszych niż 1% lub nie są uznawane za niebezpieczne zgodnie z przepisami USA dotyczącymi przekazywania informacji o zagrożeniach (29 CFR 1910.1200), dyrektywami UE dotyczącymi klasyfikacji i oznakowania substancji lub mieszanin albo Globalnie Zharmonizowanym Systemem klasyfikacji i oznakowania substancji lub mieszanin.

Sekcja 3: Skład i informacje o składnikach

3.1 Substancje

Materiał nie spełnia kryteriów uznania za substancję.

3.2 Mieszaniny

Skład					
Nazwa chemiczna	**Identyfikatory**	**%**	**LD50/LC50**	**Klasyfikacje zgodnie z rozporządzeniem/dyrektywą**	**Komentarze**
Tiocyjanian guanidyny	**CAS:** 593-84-0 **EINECS:** 209-812-1	10%–20%	593 mg/kg	**CLP UE:** Toksyczność ostra 5, H302, H313, H320 **GHS ONZ:** Toksyczność ostra 5 (doustnie); Działanie drażniące na skórę 3; Działanie drażniące na oczy 2B **OSHA HCS 2012:** Toksyczność ostra 5 (doustnie); Działanie drażniące na oczy 2B	BDD

Sekcja 4: Środki pierwszej pomocy

4.1 Opis środków pierwszej pomocy

Inhalacja Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. Wyprowadzić poszkodowaną osobę na świeże powietrze. W razie problemów z oddychaniem podać tlen. Nie stosować wentylacji metodą usta-usta, jeżeli osoba poszkodowana wdychała substancję. Zastosować sztuczne oddychanie za pomocą maski twarzowej wyposażonej w zawór jednodrożny albo innego odpowiedniego urządzenia medycznego do wentylacji. Jeżeli osoba poszkodowana nie oddycha, zastosować sztuczne oddychanie.

Skóra Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W przypadku pomniejszego kontaktu ze skórą należy unikać rozprowadzania materiału na inne części skóry. W razie kontaktu z substancją natychmiast przystąpić do płukania skóry pod bieżącą wodą przez co najmniej 20 minut. Należy zdjąć i odizolować zanieczyszczone ubranie.

Oczy	Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W razie kontaktu z substancją natychmiast przystąpić do płukania oczu pod bieżącą wodą przez co najmniej 20 minut. W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
Połknięcie	Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W razie połknięcia przepłukać usta wodą (wyłącznie jeżeli poszkodowana osoba jest przytomna). NIE wywoływać wymiotów. Jeżeli poszkodowana osoba połknęła substancję, nie wolno stosować wentylacji metodą usta-usta. W razie połknięcia należy natychmiast skorzystać z pomocy lekarza.

4.2 Najważniejsze ostre i opóźnione objawy oraz skutki narażenia

Patrz sekcja 11 — Informacje toksykologiczne.

4.3 Wskazania dotyczące wszelkiej natychmiastowej pomocy lekarskiej i szczególnego postępowania z poszkodowanym

Uwagi dla lekarza	Wdrażane leczenie powinno zależeć od zaobserwowanych objawów występujących u pacjenta. Należy rozważyć możliwość nadmiernego narażenia na materiały inne niż ten produkt.

Sekcja 5: Postępowanie w przypadku pożaru

5.1 Środki gaśnicze

Odpowiednie środki gaśnicze	DUŻE POŻARY: Proszek gaśniczy, CO2, piana odporna na działanie alkoholu lub rozpylana woda. MAŁE POŻARY: Proszek gaśniczy, CO2 lub rozpylana woda.
Niewłaściwe środki gaśnicze	Brak dostępnych danych

5.2 Szczególne zagrożenia związane z substancją lub mieszaniną

Szczególne zagrożenia związane z pożarem i wybuchem	Plastikowe kartridże zawierające odczynniki mogą emitować toksyczne opary dwutlenku węgla, tlenków siarki, tlenków azotu.
Niebezpieczne produkty spalania	Brak dostępnych danych

5.3 Informacje dla straży pożarnej

Strażacka ognioodporna odzież ochronna zapewnia ograniczoną ochronę WYŁĄCZNIE w przypadku walki z pożarem. Jest ona nieskuteczna w przypadku rozlania materiału, gdzie istnieje możliwość bezpośredniego kontaktu z substancją. Należy wówczas założyć odzież chroniącą przed chemikaliami specjalnie zalecaną przez producenta. Taka odzież może zapewniać niewielką ochronę termiczną lub nie zapewniać takiej ochrony.
Należy używać autonomiczne aparaty oddechowe (SCBA).
MAŁE POŻARY: Jeżeli można to zrobić bez ryzyka, należy wynieść pojemniki z obszaru objętego pożarem.

Sekcja 6: Postępowanie w przypadku niezamierzonego uwolnienia do środowiska

6.1 Indywidualne środki ostrożności, wyposażenie ochronne i procedury w sytuacjach awaryjnych

Indywidualne środki ostrożności	Podane indywidualne środki ostrożności mają zastosowanie w sytuacji uszkodzenia kartridża. Nosić odpowiednią odzież ochronną. Nie wchodzić w rozlany materiał. Nie dotykać uszkodzonych pojemników lub rozlanego materiału bez używania odpowiedniej odzieży ochronnej. Zapewnić wentylację zamkniętych obszarów.
Procedury awaryjne	Nie oczekuje się, aby były wymagane jakiekolwiek procedury awaryjne, jeżeli materiał będzie używany w zwykłych warunkach zgodnie z zaleceniami.

6.2 Środki ostrożności w zakresie ochrony środowiska

Zapobiegać odpływowi do dróg wodnych, kanalizacji, piwnic lub zamkniętych obszarów.

6.3 Metody i materiały zapobiegające rozprzestrzenianiu się skażenia i służące do usuwania skażenia

Metody zapobiegające rozprzestrzenianiu się skażenia i służące do usuwania skażenia	W przypadku niewielkich wycieków, założyć rękawice i zebrać wyciek ręcznikiem papierowym. Nie wylewać rozlanych materiałów do kanalizacji.

6.4 Odniesienia do innych sekcji

Patrz sekcja 8 — Kontrola narażenia/środki ochrony indywidualnej i sekcja 13 — Postępowanie z odpadami.

Sekcja 7: Postępowanie z substancjami i mieszaninami oraz ich magazynowanie

7.1 Środki ostrożności dotyczące bezpiecznego postępowania

Obchodzenie się z produktem	Nie są wymagane specjalne procedury dotyczące postępowania. W razie uszkodzenia kartridża należy unikać kontaktu z rozlanymi odczynnikami. Unikać zanieczyszczenia skóry i oczu.

7.2 Warunki bezpiecznego magazynowania, łącznie z informacjami dotyczącymi wszelkich wzajemnych niezgodności

Magazynowanie	Przechowywać zgodnie z informacjami podanymi na etykiecie produktu. Przechowywać z dala od niezgodnych materiałów. Przechowywać w zamkniętym miejscu. Pojemnik/opakowanie przechowywać ściśle zamknięte w chłodnym i dobrze wentylowanym pomieszczeniu.

7.3 Szczególne zastosowanie(-a) końcowe

Patrz sekcja 1.2 — Istotne zidentyfikowane zastosowania.

Sekcja 8: Kontrola narażenia/środki ochrony indywidualnej

8.1 Parametry kontroli

	Wartości graniczne narażenia/wytyczne			
	Wynik	**ACGIH**	**NIOSH**	**OSHA**
Tiocyjanian guanidyny	TWA	Nie ustalono	Nie ustalono	Nie ustalono

8.2 Kontrola narażenia

Techniczne środki kontroli
Należy stosować dobrą wentylację ogólną. Natężenie wentylacji należy dostosować do warunków. Jeśli dotyczy, należy stosować odpowiednie osłony procesowe, lokalną wentylację i wyciągi lub też inne środki techniczne, aby utrzymywać poziom substancji lotnych poniżej dopuszczalnych limitów narażenia. Jeżeli nie określono limitów narażenia, należy utrzymywać dopuszczalny poziom substancji lotnych.

Indywidualny sprzęt ochronny

Ochrona dróg oddechowych
Nie oczekuje się, aby sprzęt oddechowy był konieczny, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W innym przypadku należy stosować się do wytycznych organizacji OSHA, dotyczących ochrony układu oddechowego zawartych w rozdziale 29 kodeksu CFR 1910.134 lub w Normie Europejskiej EN 149. W razie przekroczenia limitów narażenia lub wystąpienia objawów należy używać odpowiedniego aparatu oddechowego zgodnego z normą NIOSH/MSHA lub Normą Europejską EN 149.

Ochrona oczu lub twarzy
Nosić okulary chroniące przed rozpryskiem substancji chemicznych.

Ochrona skóry lub ciała
Nosić odzież ochronną

Kontrola narażenia środowiska
Przestrzegać stosowanej w ośrodku najlepszej praktyki dotyczącej postępowania z odpadami oraz ich usuwania.

Legenda dotycząca skrótów
OSHA = Occupational Safety and Health Administration (Administracja ds. higieny i bezpieczeństwa pracy)
TWA = Time-Weighted Average, wartość uśredniona czasowo na podstawie narażenia 8h/dobę, 40h/tydzień

Sekcja 9: Właściwości fizyczne i chemiczne

9.1 Informacje dotyczące właściwości fizycznych i chemicznych

Opis materiału			
Postać fizyczna	Ciecz	Kolor	Bezbarwny
Zapach	Bezwonne	Próg zapachu	Brak danych
Właściwości ogólne			
Punkt wrzenia	100 °C (212 °F)	Temperatura topnienia/krzepnięcia	0 °C (32 °F)
Temperatura rozkładu	Brak danych	pH	Od 3,3 do 8,8
Ciężar właściwy/Gęstość względna	= 1 Woda =1	Rozpuszczalność w wodzie	100% rozpuszczalność
Lepkość	Brak danych	Właściwości wybuchowe	Brak danych
Właściwości utleniające:	Brak danych		
Lotność			
Prężność pary	Minimalne	Gęstość pary	Brak danych
Współczynnik parowania	Minimalne		
Łatwopalność			
Temperatura zapłonu	Brak danych	UEL	Brak danych
LEL	Brak danych	Temperatura samozapłonu	Brak danych
Palność (ciało stałe/gaz)	Brak danych		
Środowisko			
Współczynnik podziału: n-oktanol/woda	Brak danych		

9.2 Inne informacje

Nie odnotowano żadnych dodatkowych parametrów fizycznych ani chemicznych.

Sekcja 10: Stabilność i reaktywność

10.1 Reaktywność

W warunkach prawidłowego stosowania brak znanych niebezpiecznych reakcji.

10.2 Stabilność chemiczna

Produkt stabilny

10.3 Możliwość występowania niebezpiecznych reakcji

Nie dochodzi do niebezpiecznej polimeryzacji.

10.4 Warunki, których należy unikać

Materiały niezgodne. Spalające się plastikowe kartridże zawierające odczynniki mogą uwalniać toksyczne produkty uboczne

10.5 Materiały niezgodne

Kwasy.

10.6 Niebezpieczne produkty rozkładu

Spalające się plastikowe kartridże zawierające odczynniki mogą uwalniać toksyczne produkty uboczne.

Sekcja 11: Informacje toksykologiczne

11.1 Informacje dotyczące skutków toksykologicznych

Komponenty		
Tiocyjanian guanidyny	593-84-0	**Toksyczność ostra:** LD50 (śródotrzewnowo, mysz) • 593 mg/kg

Właściwości GHS	Klasyfikacja
Toksyczność ostra	**UE/CLP**•Brak danych **GHS ONZ**•Ostra toksyczność, doustnie 5 **OSHA HCS 2012**•Brak danych
Działanie żrące/drażniące na skórę	**UE/CLP**•Brak danych **GHS ONZ**•Łagodne podrażnienie skóry 3 **OSHA HCS 2012**•Brak danych
Poważne uszkodzenie/podrażnienie oczu	**UE/CLP**•Brak danych **GHS ONZ**•Łagodne podrażnienie oczu 2B **OSHA HCS 2012**•Łagodne podrażnienie oczu 2B
Uczulenie skóry	**UE/CLP**•Brak danych **GHS ONZ**•Brak danych **OSHA HCS 2012**•Brak danych
Uczulenia układu oddechowego	**UE/CLP**•Brak danych **GHS ONZ**•Brak danych **OSHA HCS 2012**•Brak danych
Rakotwórczość	**UE/CLP**•Brak danych **GHS ONZ**•Brak danych **OSHA HCS 2012**•Brak danych
Działanie mutagenne na komórki rozrodcze	**UE/CLP**•Brak danych **GHS ONZ**•Brak danych **OSHA HCS 2012**•Brak danych
Działanie toksyczne na rozrodczość	**UE/CLP**•Brak danych **GHS ONZ**•Brak danych **OSHA HCS 2012**•Brak danych
STOT-SE	**UE/CLP**•Brak danych **GHS ONZ**•Brak danych **OSHA HCS 2012**•Brak danych

Możliwy wpływ na zdrowie

Inhalacja
Ostre (natychmiastowe) Może powodować podrażnienia.
Przewlekłe (opóźnione) Brak dostępnych danych

Skóra
Ostre (natychmiastowe) Powoduje łagodne podrażnienie skóry.
Przewlekłe (opóźnione) Brak dostępnych danych

Oczy
Ostre (natychmiastowe) Powoduje podrażnienie oczu.
Przewlekłe (opóźnione) Brak dostępnych danych

Połknięcie
Ostre (natychmiastowe) W razie połknięcia może mieć szkodliwe działanie.
Przewlekłe (opóźnione) Brak dostępnych danych

Legenda dotycząca skrótów
LD = Lethal Dose, dawka śmiertelna

Sekcja 12: Informacje ekologiczne

12.1 Toksyczność

LC50 (gupik): 89,1 mg/l przez 96 h

12.2 Trwałość i zdolność do rozkładu

Niedostateczna ilość istotnych danych.

12.3 Zdolność do bioakumulacji

Niedostateczna ilość istotnych danych.

12.4 Mobilność w glebie

Niedostateczna ilość istotnych danych.

12.5 Wyniki oceny właściwości PBT i vPvB

Nie przeprowadzono ocen właściwości PBT i vPvB.

12.6 Inne szkodliwe skutki działania

Nie odnaleziono żadnych badań.

Sekcja 13: Postępowanie z odpadami

13.1 Postępowanie z odpadami

Odpady produktu	Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.
Odpady opakowań	Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.

13.2 Inne informacje

Próbki biologiczne, wyroby do przenoszenia i użyte kartridże należy traktować jako mogące przenosić czynniki zakaźne i wymagające zachowania standardowych środków ostrożności. Należy przestrzegać obowiązujących w placówce procedur dotyczących odpadów środowiskowych w zakresie odpowiedniego usuwania użytych kartridży i nieużytych odczynników. Te materiały mogą stanowić niebezpieczne materiały chemiczne, których usuwanie musi się odbywać zgodnie z krajowymi lub regionalnymi przepisami dotyczącymi usuwania. Jeśli krajowe lub regionalne przepisy nie regulują kwestii dotyczących odpowiedniego usuwania, wówczas próbki biologiczne i użyte kartridże należy usuwać zgodnie z wytycznymi Światowej Organizacji Zdrowia (World Health Organization, WHO) dotyczącymi obsługi i usuwania odpadów medycznych.

Sekcja 14: Informacje dotyczące transportu

	14.1 Numer UN (numer ONZ)	14.2 Prawidłowa nazwa przewozowa UN	14.3 Klasa(-y) zagrożenia w transporcie	14.4 Grupa pakowania	14.5 Zagrożenia dla środowiska
DOT	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy
TDG	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy
IMO/IMDG	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy
IATA/ICAO	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy

14.6 Szczególne środki ostrożności dla użytkowników

Brak podanych.

14.7 Transport luzem zgodnie z załącznikiem II do konwencji MARPOL 73/78 i kodeksem IBC

Nieistotne.

Sekcja 15: Informacje dotyczące przepisów prawnych

15.1 Przepisy prawne dotyczące bezpieczeństwa, ochrony zdrowia i środowiska specyficzne dla substancji lub mieszaniny

Klasyfikacja zagrożeń SARA Ostre

Wykaz						
Składnik	**CAS**	**Kanada DSL**	**Kanada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Tiocyjanian guanidyny	593-84-0	Tak	Nie	Tak	Nie	Tak

Kanada

Dotyczące pracy

Kanada — WHMIS — Klasyfikacja substancji
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

Kanada — WHMIS — Lista składników podlegających obowiązkowemu ujawnieniu
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

Dotyczące środowiska

Kanada — CEPA — Lista substancji priorytetowych
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

Stany Zjednoczone

Dotyczące pracy

USA — OSHA — Zarządzanie bezpieczeństwem procesów — wysoce niebezpieczne substancje chemiczne
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — OSHA — Substancje chemiczne podlegające konkretnym regulacjom
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

Dotyczące środowiska

USA — CAA (Clean Air Act, Ustawa o Czystym Powietrzu) — 1990 niebezpiecznych substancji zanieczyszczających powietrze
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — CERCLA/SARA — Substancje niebezpieczne oraz ich zgłaszalne ilości
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — CERCLA/SARA — Radionuklidy oraz ich zgłaszalne ilości
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — CERCLA/SARA — Sekcja 302, zgłaszalne ilości niezwykle niebezpiecznych substancji
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — CERCLA/SARA — Sekcja 302, progowe ilości planowe (TPQ) niezwykle niebezpiecznych substancji
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — CERCLA/SARA — Sekcja 313 — Raportowanie emisji
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

USA — CERCLA/SARA — Sekcja 313 — Wykaz chemikaliów PBT
- Tiocyjanian guanidyny — 593-84-0 — Nie figuruje

Stany Zjednoczone — Kalifornia

Dotyczące środowiska

USA — Kalifornia — Sprawa 65 — Wykaz karcynogenów		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Toksyczność rozwojowa		
•Tiocyjanian guanidyny	593-84-0	*Nie figuruje*
USA — Kalifornia — Sprawa 65 — Maksymalne dopuszczalne poziomy dawki (MADL)		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Poziomy braku istotnego zagrożenia (NSRL)		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Toksyczność reprodukcyjna — Kobiety		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Toksyczność reprodukcyjna — Mężczyźni		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje

15.2 Ocena bezpieczeństwa chemicznego

Nie przeprowadzono oceny bezpieczeństwa chemicznego.

Sekcja 16: Inne informacje

Stosowne zwroty (numer i pełny tekst):

H302 — Działa szkodliwie po połknięciu
H313 — Może działać szkodliwie w kontakcie ze skórą
H320 — Powoduje podrażnienie oczu

Oświadczenie dotyczące odpowiedzialności

Powyższe informacje bazują na dostępnych dla nas danych i uważamy je za prawidłowe. Ponieważ informacje mogą być stosowane w warunkach poza naszą kontrolą i których możemy nie znać, nie przyjmujemy jakiejkolwiek odpowiedzialności za wyniki ich wykorzystywania, a wszystkie osoby otrzymujące te informacje muszą we własnym zakresie określić działania, właściwości, zabezpieczenia oraz metody usuwania dotyczące konkretnych warunków. Nie udziela się żadnych gwarancji, wyrażonych czy dorozumianych (w tym gwarancji pokupności lub przydatności do określonego celu) w odniesieniu do materiałów, dokładności niniejszych informacji, wyników uzyskanych w toku wykorzystywania ani zagrożeń powiązanych z używaniem tego materiału. Należy zachować ostrożność podczas pracy z materiałem i przy jego używaniu. Powyższe informacje są przekazywane w dobrej wierze i są uznawane za dokładne. Na dzień publikacji przekazujemy wszystkie informacje stosowne do przewidywalnych zastosowań materiału. Jednakże w sytuacji wystąpienia niepożądanego incydentu skojarzonego z produktem niniejsza karta charakterystyki substancji nie stanowi zastępstwa dla konsultacji z odpowiednio przeszkolonym personelem.

Legenda dotycząca skrótów
BDD = Brak dostępnych danych

Ficha de dados de segurança
Data de entrada em vigor: Janeiro 2021
Data de substituição: Setembro 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-COV-2/Flu/RSV

Secção 1: Identificação da Substância/Mistura e da Empresa/Projeto

1.1 Identificador do Produto

Nome do Produto	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Código do Produto	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Usos relevantes da substância ou mistura identificados, e usos não recomendados

Uso(s) relevante(s) identificado(s)	Utilização laboratorial

1.3 Detalhes do fornecedor da ficha de dados de segurança do material

Fabricante		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US: techsupport@cepheid.com
	Telefone (Geral)	1 (888) 838-3222 - Opção 2 (EUA)
	Telefone (Geral)	1 (408) 541-4191 - Fora dos EUA
Fornecedor		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Suécia www.cepheidinternational.com EU: support@cepheideurope.com
	Telefone (Geral)	+33 563 825 319
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefone (Austrália)	1800 107 884

1.4 Número de telefone de emergência

Fabricante	1 (800) 535-5053 - INFOTRAC - Emergência durante 24 h
Fabricante	1 (352) 323-3500 - Fora dos EUA

Secção 2: Identificação dos Perigos

UE/CEE

Segundo: Regulamentação (CE) N.º 1272/2008 (CLP)/REACH 1907/2006 [alterada pela 453/2010]

2.1 Classificação da substância ou mistura

CLP

A seguinte ficha de dados de segurança (FDS) refere-se à mistura de produto final completo apenas conforme utilizado no laboratório. O produto contém esferas e reagentes no cartucho ou nos recipientes à parte. As isenções para a divulgação de informações sobre alguns componentes estão em conformidade com o Artigo 1(5)(d) do CLP e da secção 29 1910.1200(g)(2)(i)(C)(1) e (2) do CFR.
Não classificado

2.2 Elementos do rótulo

CLP

Declarações de risco

Não são necessários elementos do rótulo.

2.3 Outros perigos

CLP

Este material não é considerado perigoso conforme Regulamentação (CE) N.º 1272/2008 (CLP).

GHS da ONU (Rotulagem utilizada em produtos)

Segundo: Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS) da ONU

2.1 Classificação da substância ou mistura

GHS da ONU

Toxicidade oral aguda 5
Irritação cutânea ligeira 3
Irritação ocular leve 2B

2.2 Elementos do rótulo

GHS da ONU

AVISO

Declarações de perigo

Nocivo por ingestão.
Pode ser nocivo em contacto com a pele.
Provoca irritação ocular.

Declarações de precaução

Prevenção

Lavar as mãos cuidadosamente após manuseamento.

Resposta

Em caso de irritação cutânea: consulte um médico.
SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar.
Caso a irritação ocular persista: consulte um médico.
Caso sinta indisposição, contacte um CENTRO DE INFORMAÇÃO ANTIVENENOS ou um médico.

2.3 Outros perigos

GHS DA ONU Este produto é considerado perigoso de acordo com o Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS).

Estados Unidos da América (EUA)

Segundo: OSHA 29 CFR 1910.1200 HCS

2.1 Classificação da substância ou mistura

OSHA HCS 2012 Irritação ocular ligeira 2B

2.2 Elementos do rótulo

OSHA HCS 2012

Declarações de perigo
Nocivo por ingestão.
Pode ser nocivo em contacto com a pele.
Provoca irritação ocular.

Declarações de precaução

Prevenção Lavar as mãos cuidadosamente após manuseamento.

Resposta SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. As lentes de contacto, caso estejam presentes, deverão ser retiradas, se tal for possível. Continuar a enxaguar.
Caso a irritação ocular persista: consultar um médico.

2.3 Outros Perigos

OSHA HCS 2012 Este produto não é considerado perigoso ao abrigo da Regulamentação dos Estados Unidos da América (Norma sobre Comunicação de Riscos - 29 CFR 1910.1200).

Canadá

Segundo: Canadá - Sistema de Informação sobre Perigos Materiais no Ambiente Laboral (WHMIS)

2.1 Classificação da substância ou mistura

WHMIS Não classificado

2.2 Elementos do rótulo

WHMIS Não são necessários elementos do rótulo.

2.3 Outros Perigos

WHMIS No Canadá, o produto acima referido não é considerado perigoso ao abrigo do Sistema de Informação de Materiais Perigosos no Local de Trabalho (WHMIS).

2.4 Outras informações

Todos os restantes reagentes, esferas e outros constituintes da mistura estão em concentrações inferiores a 1% ou não são considerados perigosos ao abrigo das regulamentações de comunicação de perigos (29 CFR 1910.1200), das diretivas da UE para a classificação e rotulagem de substâncias ou misturas ou do Sistema Mundial Harmonizado para a classificação e rotulagem de substâncias ou misturas.

Secção 3: Composição/Informações sobre os Ingredientes

3.1 Substâncias

O material não cumpre os critérios de uma substância.

3.2 Misturas

Composição					
Nome do produto químico	**Identificadores**	**%**	**LD50/LC50**	**Classificações de acordo com regulamentos/diretivas**	**Comentários**
Tiocianato de guanidina	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**UE CLP:** Tox. aguda 5, H302, H313, H320 **GHS da ONU:** Tox. aguda 5 (oral); Irrit. pele 3; Irrit. ocular 2B **OSHA HCS 2012:** Tox. aguda 5 (oral); Irrit. olhos 2B	Nenhuns dados disponíveis

Secção 4: Medidas de Primeiros Socorros

4.1 Descrição das medidas de primeiros socorros

Inalação Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Mover a vítima para o ar livre. Administrar oxigénio se a respiração estiver difícil. Não usar o método boca-a-boca se a vítima tiver inalado a substância; ministre respiração artificial com o auxílio de uma máscara de bolso equipada com uma válvula de 1 via ou outro dispositivo médico de respiração adequado. Administrar respiração artificial se a vítima não estiver a respirar.

Pele Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Para um pequeno contacto com a pele, evitar espalhar o material pela pele não afetada. Em caso de contacto com a substância, lavar imediatamente a pele com água corrente por pelo menos 20 minutos. Despir e isolar a roupa contaminada.

Olhos Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de contacto com a substância, lavar imediatamente os olhos com água corrente por pelo menos 20 minutos. Caso a irritação ocular persista: consultar um médico.

Ingestão Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de ingestão, lavar a boca com água (apenas se a pessoa estiver consciente). NÃO provocar o vómito. Não usar o método boca-a-boca se a vítima tiver ingerido a substância. Em caso de ingestão, consultar um médico imediatamente.

4.2 Sintomas e efeitos mais importantes, tanto agudos quanto retardados

Consultar a Secção 11 - Informação Toxicológica.

4.3 Indicação de qualquer cuidado médico imediato e tratamento especial necessários

Notas para o Médico Todos os tratamentos devem basear-se nos sinais e sintomas de perturbações observados no paciente. Deve ser considerada a possibilidade de sobrexposição a outros materiais além deste produto.

Secção 5: Medidas de Combate a Incêndios

5.1 Meios de extinção

Meios de extinção adequados	GRANDES INCÊNDIOS: Produto químico seco, CO2, espuma resistente ao álcool ou água pulverizada. PEQUENOS INCÊNDIOS: Produto químico seco, CO2 ou água pulverizada.
Meios de extinção inadequados	Sem dados disponíveis

5.2 Perigos especiais provocados pela substância ou mistura

Perigos de Incêndios e Explosões Incomuns	Cartucho de plástico contendo reagentes que podem emitir vapores tóxicos de óxidos de carbono, óxidos de enxofre e óxidos de azoto.
Produtos de Combustão Perigosos	Sem dados disponíveis

5.3 Conselhos para bombeiros

Roupas protetoras estruturais de bombeiros fornecem APENAS proteção limitada em caso de incêndio; não são eficientes em situações de derramamentos, onde é possível o contacto direto com a substância.
Usar roupa protetora contra produtos químicos que seja especificamente recomendada pelo fabricante. Poderá fornecer proteção térmica mínima ou nenhuma proteção.
Usar aparelho de respiração autónomo de pressão positiva (SCBA).
PEQUENOS INCÊNDIOS: Se não houver perigos, mover os recipientes da área de incêndio.

Secção 6: Medidas contra Libertação Acidental

6.1 Precauções individuais, equipamento protetor e procedimentos em emergências

Precauções pessoais	No caso de um cartucho se partir, aplicam-se estas precauções de proteção individual. Usar vestuário de proteção adequado. Não andar sobre material derramado. Não tocar em recipientes danificados ou material derramado a não ser que tenha vestuário de proteção adequado. Ventilar áreas fechadas.
Procedimentos de Emergência	Não se prevê a necessidade de procedimentos de emergência se o material for usado em condições normais e de acordo com as recomendações.

6.2 Precauções ambientais

Evitar a entrada em cursos de água, esgotos, caves ou áreas confinadas.

6.3 Métodos e material para contenção e limpeza

Medidas de Contenção/Limpeza	Em caso de derrames pequenos, usar luvas e absorver o derrame com papel absorvente. Não eliminar os materiais derramados através da canalização.

6.4 Referências para outras seções

Consultar a Secção 8 - Controlo da Exposição/Proteção Individual e a Secção 13 - Considerações relativas à eliminação.

Secção 7: Manuseamento e armazenamento

7.1 Precauções para o manuse amento seguro

Manuseio Não necessita de manuseamento especial. Se o cartucho se partir, evitar o contacto com os reagentes derramados. Evitar o contacto com a pele e os olhos.

7.2 Condições para armazenamento seguro, incluindo quaisquer incompatibilidades

Armazenamento Armazenar de acordo com a documentação do produto. Manter afastado de materiais incompatíveis. Armazenar em local fechado à chave. Guardar o recipiente/embalagem bem fechado em local fresco e bem ventilado.

7.3 Utilização(ões) Final(is) Específica(s)

Consultar a Secção 1.2 - Utilizações identificadas relevantes.

Secção 8: Controlos e Exposição/Proteção Individual

8.1 Parâmetros de controlo

	Limites de Exposição/Orientações			
	Resultado	**ACGIH**	**NIOSH**	**OSHA**
Tiocianato de guanidínio	TWA	Não estabelecidos	Não estabelecidos	Não estabelecidos

8.2 Controlos de exposição

Medidas/Controlos de Engenharia Deve usar-se uma boa ventilação geral. Os níveis de ventilação devem estar adequados às condições. Se aplicável, usar confinamento de processos, ventilação por exaustão local ou outro controlo técnico para manter os níveis de partículas disseminadas por via aérea em suspensão abaixo dos limites de exposição recomendados. Caso não tenham sido definidos limites, manter os níveis destas partículas em suspensão num nível aceitável.

Equipamento de Proteção Individual

Respiratório Não deve ser necessário equipamento respiratório se o material for utilizado nas condições normais e conforme recomendado. Caso contrário, siga as regulamentações do aparelho de respiração OSHA que se encontram na norma 29 CFR 1910.134 ou na Norma Europeia EN 149. Em caso de ultrapassagem dos limites de exposição ou da ocorrência de sintomas, usar um aparelho de respiração aprovado pelo NIOSH/MSHA ou pela Norma Europeia EN 149.

Olhos/Face Usar óculos de proteção contra salpicos de produtos químicos.

Pele/Corpo Usar vestuário de proteção

Controlos Ambientais de Exposição Seguir as melhores práticas para gestão do local e eliminação dos resíduos.

Chave para abreviaturas
OSHA = Agência para a Segurança e Saúde no Trabalho
TWA = A Média Ponderada tem por base a exposição 8 h/dia, 40 h/semana

Secção 9: Propriedades Físicas e Químicas

9.1 Informações sobre Propriedades Físicas e Químicas

Descrição do material			
Forma física	Líquido	Cor	Incolor
Odor	Inodoro	Limiar do Odor	Dados em falta
Propriedades Gerais			
Ponto de ebulição	100 °C (212 °F)	Ponto de fusão/Ponto de congelamento	0 °C (32 °F)
Temperatura de decomposição	Dados em falta	pH	3,3 a 8,8
Gravidade específica/Densidade relativa	= 1 Água =1	Solubilidade em água	100% solúvel
Viscosidade	Dados em falta	Propriedades explosivas:	Dados em falta
Propriedades Oxidantes:	Dados em falta		
Volatilidade			
Pressão do vapor	Mínima	Densidade do vapor	Dados em falta
Taxa de evaporação	Mínima		
Inflamabilidade			
Ponto de inflamação	Dados em falta	UEL	Dados em falta
LEL	Dados em falta	Autoignição	Dados em falta
Inflamabilidade (sólido/gasoso):	Dados em falta		
Ambiental			
Coeficiente de partição octanol/água	Dados em falta		

9.2 Outras Informações

Não foram observados parâmetros físico-químicos adicionais.

Secção 10: Estabilidade e Reatividade

10.1 Reatividade

Desconhecida reação perigosa em condições normais de utilização.

10.2 Estabilidade química

Estável

10.3 Possibilidade de reações perigosas

Não haverá polimerização perigosa.

10.4 Condições a evitar

Materiais incompatíveis. A queima do cartucho de plástico contendo reagentes pode libertar derivados tóxicos.

10.5 Materiais incompatíveis

Ácidos.

10.6 Produtos de decomposição perigosos

A queima do cartucho de plástico contendo reagentes pode libertar derivados tóxicos.

Secção 11: Informações Toxicológicas

11.1 Informações sobre efeitos toxicológicos

Componentes		
Tiocianato de guanidínio	593-84-0	**Toxicidade aguda:** Intraperitoneal-Ratinho LD50 • 593 mg/kg

Propriedades do GHS	Classificação
Toxicidade aguda	**UE/CLP**•Dados em falta **ONU GHS**•Toxicidade Aguda - Oral - Categoria 5 **OSHA HCS 2012**•Dados em falta
Corrosão/irritação cutânea	**UE/CLP**•Dados em falta **ONU GHS**•Irritação cutânea ligeira Categoria 3 **OSHA HCS 2012**•Dados em falta
Lesão/irritação ocular grave	**UE/CLP**•Dados em falta **ONU GHS**• Irritação ocular ligeira Categoria 2B **OSHA HCS 2012**•Irritação ocular ligeira Categoria 2B
Sensibilização da pele	**UE/CLP**•Dados em falta **ONU GHS**•Dados em falta **OSHA HCS 2012**•Dados em falta
Sensibilização respiratória	**UE/CLP**•Dados em falta **ONU GHS**•Dados em falta **OSHA HCS 2012**•Dados em falta
Carcinogenicidade	**UE/CLP**•Dados em falta **ONU GHS**•Dados em falta **OSHA HCS 2012**•Dados em falta
Mutagenicidade de células germinativas	**UE/CLP**•Dados em falta **ONU GHS**•Dados em falta **OSHA HCS 2012**•Dados em falta
Toxicidade da reprodução	**UE/CLP**•Dados em falta **ONU GHS**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-SE	**UE/CLP**•Dados em falta **ONU GHS**•Dados em falta **OSHA HCS 2012**•Dados em falta

Potenciais efeitos na saúde

Inalação
Agudo (Imediato) Pode provocar irritação.
Crónico (Retardado) Sem dados disponíveis
Pele
Agudo (Imediato) Provoca irritação cutânea ligeira.
Crónico (Retardado) Sem dados disponíveis
Olhos
Agudo (Imediato) Causa irritação ocular.
Crónico (Retardado) Sem dados disponíveis
Ingestão
Agudo (Imediato) Pode ser nocivo em caso de ingestão.
Crónico (Retardado) Sem dados disponíveis

Chave para abreviaturas
LD = Dose Letal

Secção 12: Informações Ecológicas

12.1 Toxicidade

LC50 (guppy): 89,1 mg/l @ 96 h

12.2 Persistência e degradabilidade

Dados dos materiais em falta.

12.3 Potencial bioacumulativo

Dados dos materiais em falta.

12.4 Mobilidade no solo

Dados dos materiais em falta.

12.5 Resultados de avaliação PBT e vPvB

Não foi feita a avaliação PB e vPvB.

12.6 Outros efeitos adversos

Não foram encontrados estudos.

Secção 13: Considerações sobre a Eliminação

13.1 Métodos de tratamento de dejetos

Produto residual	Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.
Embalagem residual	Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

13.2 Outras informações

Amostras biológicas, dispositivos de transferência e cartuchos usados devem ser considerados como tendo potencial de transmissão de agentes infeciosos que exigem precauções padrão. Siga os procedimentos relativos a resíduos ambientais da sua instituição relativamente à eliminação correta de cartuchos usados e reagentes não usados. Estes materiais podem apresentar características de resíduos químicos perigosos que exigem procedimentos de eliminação nacionais ou regionais específicos. Se as regulamentações nacionais ou regionais não disponibilizarem uma indicação clara sobre a eliminação correta, as amostras biológicas e os cartuchos usados devem ser eliminados de acordo com as diretrizes relativas ao manuseamento e à eliminação de resíduos médicos da OMS (Organização Mundial da Saúde).

Secção 14: Informações sobre Transporte

	14.1 Nome na ONU	14.2 Nome de transporte adequado (ONU)	14.3 Classe(s) de transporte de risco	14.4 Grupo de embalagem	14.5 Perigos ambientais
DOT	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável
TDG	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável
IMO/IMDG	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável
IATA/ICAO	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável

14.6 Precauções especiais para o utilizador

Nenhum conhecido.

14.7 Transporte a granel segundo o Anexo II de MARPOL 73/78 e o código do IBC

Nenhuma especificada.

Secção 15: Informações Regulamentares

15.1 Regulamentos/legislação de segurança, saúde e ambientais, específicos da substância ou mistura

Classificações de Risco SARA Agudo

Inventário						
Componente	**CAS**	**DSL (Canada)**	**NDSL**	**EINECS (UE)**	**ELNICS (UE)**	**TSCA**
Tiocianato de guanidínio	593-84-0	Sim	Não listado	Sim	Não listado	Sim

Canadá

Trabalho

Canadá - WHMIS - Classificação de Substâncias
•Tiocianato de guanidínio 593-84-0 Não listado

Canadá - WHMIS - Lista de Divulgação de Ingredientes
•Tiocianato de guanidínio 593-84-0 Não listado

Ambiente

Canadá - CEPA - Lista de Substâncias Prioritárias
•Tiocianato de guanidínio 593-84-0 Não listado

Estados Unidos da América

Trabalho

E.U.A. - OSHA - Gestão de Segurança do Processo - Produtos Químicos Altamente Perigosos
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - OSHA - Químicos com Regulamentação Específica
•Tiocianato de guanidínio 593-84-0 Não listado

Ambiente

E.U.A. - CAA (Lei do Ar Puro) - 1990 Poluentes Atmosféricos Perigosos
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - CERCLA/SARA - Substâncias Perigosas e Respetivas Quantidades de Notifica Obrigatória
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - CERCLA/SARA - Radionuclídeos e Respetivas Quantidades de Comunicação Obrigatória
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - CERCLA/SARA - Secção 302 Quantidades de Comunicação Obrigatória de Substâncias Extremamente Perigosas da EPCRA
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - CERCLA/SARA - Secção 302 Planeamento de Quantidades Limite de Substâncias Extremamente Perigosas
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - CERCLA/SARA - Secção 313 - Relatório de Emissão
•Tiocianato de guanidínio 593-84-0 Não listado

E.U.A. - CERCLA/SARA - Secção 313 - Listagem de Produtos Químicos PBT
•Tiocianato de guanidínio 593-84-0 Não listado

Estados Unidos da América - Califórnia

Ambiente

E.U.A. - Califórnia - Proposta 65 - Lista de Substâncias Cancerígenas		
•Tiocianato de guanidínio	593-84-0	*Não listado*
E.U.A. - Califórnia - Proposta 65 - Toxicidade para o Desenvolvimento		
•Tiocianato de guanidínio	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Níveis Máximos de Dose Permitidos (MADL)		
•Tiocianato de guanidínio	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Sem Níveis de Risco Significativos (NSRL)		
•Tiocianato de guanidínio	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Mulheres		
•Tiocianato de guanidínio	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Homens		
•Tiocianato de guanidínio	593-84-0	Não listado

15.2 Avaliação da Segurança Química

Não foi efetuada qualquer Avaliação da Segurança Química.

Secção 16: Outras Informações

Frases relevantes (código e texto)

H302 – Nocivo por ingestão.
H313 – Pode ser nocivo em contacto com a pele.
H320 – Provoca irritação ocular.

Renúncia/Declaração de Responsabilidade

A informação supramencionada baseia-se em dados que nos foram disponibilizados e é tida como correta. Dado que a informação pode ser aplicada em condições fora do nosso controlo e com as quais podemos não estar familiarizados, não assumimos qualquer responsabilidade pelo resultado da sua utilização, e todas as pessoas que a recebam têm de determinar individualmente os efeitos, as propriedades, as proteções e os procedimentos de eliminação que se aplicam às suas condições particulares. Não se assume qualquer representação ou garantia, implícita ou explicitamente (incluindo garantia de adequação ou comerciabilidade para uma finalidade específica) em relação aos materiais, à exatidão desta informação, aos resultados obtidos decorrentes da sua utilização ou a perigos relacionados com a utilização deste material. Deve-se ter cuidado no manuseamento e utilização deste material. A informação anterior é disponibilizada de boa-fé e é tida como exata. À data de emissão, fornecemos toda a informação relevante para um manuseamento previsível do material. No entanto, caso ocorra um incidente adverso associado a este produto, esta ficha de dados de segurança não substitui, nem se pretende que substitua, a consulta de um profissional com formação adequada.

Chave para abreviaturas
NDA = Nenhuns Dados Disponíveis

Säkerhetsdatablad
Giltighetsdatum: Januari 2021
Ersätter datum: September 2020

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Avsnitt 1: Namn på ämnet/blandningen och bolaget/företaget

1.1 Produkt-ID

Produktnamn	**Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**
Produktkod	900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Relevant identifierade användning av ämnet eller blandningen och användningar som det avråds från

Relevant identifierade användning (ar)	Laboratorieanvändning

1.3 Detaljer om säkerhetsdatabladets leverantör

Tillverkare		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US: techsupport@cepheid.com
	Telefon (allmän)	1 (888) 838-3222 - USA alt.2
	Telefon (allmän)	1 (408) 541-4191 - Utanför USA
Leverantör		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sverige www.cepheidinternational.com EU: support@cepheideurope.com
	Telefon (allmän)	+33 563 825 319
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australien www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefon (Australien)	1800 107 884

1.4 Larmnummer

Tillverkare	1 (800) 535-5053 - INFOTRAC - 24 tim Akutfall
Tillverkare	1 (352) 323-3500 - Utanför USA

Avsnitt 2: Farliga egenskaper

EU/EEG

Enligt: EU direktiv 1272/2008 (CLP) /REACH 1907/2006 [ändrad genom 453/2010]

2.1 Klassificering av ämnet eller blandningen

CLP

Följande säkerhetsdatablad avser endast den färdiga blandningsprodukten som den används i laboratorium. Produkten innehåller pärlor och reagens i kassetten eller i separata behållare. Undantag från att avslöja en del information om vissa komponenter gäller enligt CLP Article 1(5)(d) och 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Inte klassficerad

2.2 Märkta element

CLP

Faroangivelser Inga märkta element erfordras.

2.3 Andra faror

CLP

Enligt förordning (EG) Nr 1272/2008 (CLP) anses detta material inte vara farligt.

FN GHS (Etiketteringsinnehåll som används på produkter)

Enligt: Förenta Nationernas Globally Harmonized Standard for Classification and Labeling (GHS)

2.1 Klassificering av ämnet eller blandningen

FN GHS

Akut toxicitet - oral 5
Mild hudirritation 3
Mild ögonirritation 2B

2.2 Märkta element

FN GHS

VARNING

Riskuttalande

Farligt vid förtäring.
Kan vara skadligt vid hudkontakt.
Orsakar ögonirritation.

Skyddsangivelser

Förebyggande Tvätta Händer noggrant efter hantering.

Svar Vid hudirritation: Sök läkarhjälp.
VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja.
Vid bestående ögonirritation: Sök läkarhjälp.
Vid obehag, kontakta GIFTINFORMATIONSCENTRAL eller läkare.

2.3 Andra faror

FN GHS — Enligt Globally Harmonized Standard for Classification and Labeling (GHS) anses den här produkten vara farlig.

Förenta staterna (USA)
Enligt: OSHA 29 CFR 1910.1200 HCS

2.1 Klassificering av ämnet eller blandningen

OSHA HCS 2012 — Mild ögonirritation 2B

2.2 Märkta element

OSHA HCS 2012

Riskuttalande — Skadligt vid förtäring.
Kan vara skadligt vid hudkontakt.
Orsakar ögonirritation.

Skyddsangivelser

Förebyggande — Tvätta Händer noggrant efter hantering.

Svar — VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja.
Vid bestående ögonirritation: Sök läkarhjälp.

2.3 Andra faror

OSHA HCS 2012 — Enligt United States Regulations (29 CFR 1910.1200 – Riskkommunikationsstandard), anses produkten inte vara farlig.

Kanada
Enligt: WHMIS

2.1 Klassificering av ämnet eller blandningen

WHMIS — Inte klassficerad

2.2 Märkta element

WHMIS — Inga märkta element erfordras.

2.3 Andra faror

WHMIS — I Kanada anses produkten som nämns ovan inte vara en riskprodukt enligt Workplace Hazardous Materials Information System (WHMIS) (Material informationssystem för arbetsplatsrisker).

2.4 Övrig information

Alla andra reagenser, kulor, och andra beståndsdelar har koncentrationer som är mindre än 1 % i blandningen eller anses inte farliga enligt amerikanska regler för riskkommunikation (29 CFR 1910.1200), EU-direktiv för klassificering och märkning av ämnen eller blandningar eller Global Harmonization System för klassificering och märkning av ämnen eller blandningar.

Avsnitt 3: Sammansättning/Information om beståndsdelar

3.1 Ämnen

Materialet uppfyller inte kriteria för ett ämne.

3.2 Blandningar

Sammansättning					
Kemiskt namn	**Identifierare**	**%**	**LD50/LC50**	**Klassificeringar enligt förordning/direktiv**	**Kommentarer**
Guanidintiocyanat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10 % till 20 %	593 mg/kg	**EG CLP:** Akut tox. 5, H302, H313, H320 **FN GHS:** Akut tox. 5 (orl); Hudirrit. 3; Ögonirrit. 2B **OSHA HCS 2012:** Akut tox. 5 (orl); Ögonirrit. 2B	INGA DATA TILLGÄNGLIGA

Avsnitt 4: Åtgärder vid första hjälpen

4.1 Beskrivning av åtgärder vid första hjälpen

Inandning Det finns ingen behov för första hjälpen om materialet används som avsett och rekommenderat. För personen till frisk luft. Ge syrgas vid besvärad andning. Använd inte mun mot mun metoden om den drabbade svalt ämnet, ge konstgjord andning med mask utrustad med en envägsventil eller med annan lämplig medicinsk andningsutrustning. Konstgjord andning om den drabbade inte andas.

Hud Det finns ingen behov för första hjälpen om materialet används som avsett och rekommenderat. Vid mindre hudkontakt, undvik att sprida materialet på övrig hud. Vid kontakt skölj med rikliga mängder vatten i minst 20 min. Ta bort kontaminerad klädsel.

Ögon Det finns ingen behov för första hjälpen om materialet används som avsett och rekommenderat. Vid kontakt skölj med rikliga mängder vatten i minst 20 min. Vid bestående ögonirritation: Sök läkarhjälp.

Förtäring Det finns ingen behov för första hjälpen om materialet används som avsett och rekommenderat. Vid förtäring skölj munnen med vatten (endast om personen är vid medvetande). Framkalla INTE kräkning. Använd inte mun mot mun metoden om den drabbade svalt ämnet. Sök läkarvård omedelbart vid förtäring.

4.2 De viktigaste symptomen och effekterna, både akuta och fördröjda

Se avsnitt 11-toxikologisk Information.

4.3 Indikation på omedelbar medicinsk vård och vid behov specialbehandling

Läkaranvisningar Alla behandlingar bör baseras på observerade tecken och symtom på ångest hos patienten. Hänsyn bör tas till möjligheten att överexponering för andra material än den här produkten material kan ha skett.

Avsnitt 5: Brandbekämpningsåtgärder

5.1 Släckmedel

Lämpliga släckmedel STORA BRÄNDER: Torr kemikalie, CO2, alkoholresistent skum eller vattenspray. MINDRE BRÄNDER:Torra kemikalier, CO2 eller vattenspray.

Olämpliga bekämpningsmedel Inga data tillgängliga

5.2 Särskilda faror som upp står hos ämnet eller blandningen

Ovanliga brand- eller explosionsrisker	Plastkassetter som innehåller reagenser kan avge giftiga ångor av koloxider, svaveloxider, kväveoxider.
Farliga förbränningsprodukter	Inga data tillgängliga

5.3 Råd till brandbekämpningspersonal

Skyddsklädsel för brandmän som bekämpar byggnadskonstruktioner ger bara begränsat skydd ENDAST brandsituationer; den fungerar inte vid spillsituationer där direktkontakt med materialet kan förekomma.
Använd skyddsklädsel specifikt rekommenderad av tillverkaren. Den kan ge lite eller inget termiskt skydd.
Använd alltid andningsapparat med övertryck (SCBA).
MINDRE BRÄNDER: Flytta behållare från brandområdet om det är möjligt utan risk.

Avsnitt 6: Åtgärder vid oavsiktliga utsläpp

6.1 Personliga försiktighetsåtgärder, skyddsutrustning och förfaranden i nödsituationer

Personliga försiktighetsåtgärder	I den händelse att kassetten är trasig är dessa personliga försiktighetsåtgärder tillämpliga. Använd lämplig skyddsklädsel. Gå inte genom spillt material. Rör inte skadade behållare eller spillt material utan lämplig skyddklädsel. Ventilera stängda utrymmen.
Förfaranden i nödsituationer	Inga nödsituationer förväntas om materialet används under vanliga omständigheter och enligt rekommendationer.

6.2 Miljömässiga säkerhetsåtgärder

Förhindra spridning till vattenvägar, avlopp, källare eller slutna utrymmen.

6.3 Metoder och material för inneslutning och sanering

Inneslutning/ saneringsåtgärder	För mindre spill, använd handskar och absorbera spill med pappershandduk. Avyttra inte spillt material i avlopp.

6.4 Referenser till andra avsnitt

Se avsnitt 8 - exponeringskontroll/personligt skydd och avsnitt 13 - avfallshantering.

Avsnitt 7: Hantering och lagring

7.1 Försiktighetsåtgärder för säker hantering

Hantering	Ingen särskild hantering är nödvändig. Undvik kontakt med utspilld reagenser om en kassett är trasig. Undvik kontakt med hud och ögon.

7.2 Förhållanden för säker lagring, inklusive eventuell oförenlighet

Förvaring	Förvara enligt produktmärkning. Håll borta från inkompatibla material. Förvaras inlåst. Förvara behållare/förpackning väl tillsluten svalt och med ordentlig ventilation.

7.3 Specifik slutanvändning

Se avsnitt 1.2 - identifierade relevanta frågor.

Avsnitt 8: Begränsning av exponeringen/personligt skydd

8.1 Kontrollparametrar

	Gränsvärden/riktlinjer för exponering			
	Resultat	**ACGIH**	**NIOSH**	**OSHA**
Guanidintiocyanat	TWA	Ej fastställt	Ej fastställt	Ej fastställt

8.2 Begränsning av exponeringen

Tekniska åtgärder/kontroller Ordentlig ventilation skall ombesörjas. Ventilationaltionshastigheten skall överensstämma med situationen. Om tillämpligt använd processinneslutning, punktutsug eller annan lösning som håller luftburna nivåer under rekommenderade exponeringsgränser. OM exponeringsgränsen inte fastställts, håll luftburna nivåer på en acceptabel nivå

Personlig skyddsutrustning

Respiratoriska Det förväntas inget behov av andningsutrustning om materialet används under normala omständigheter och enligt det som är rekommenderat. Om det ändå används ska OSHA-reglerna för andningsutrustning följas i enlighet med 29 CFR 1910.134 eller European Standard EN 149. Använd NIOSH/MSHA eller European Standard EN 149 godkänd andningsutrustning om exponeringsgränserna överskrids eller symptom förekommer.

Ögon/ansikte Använd stänkskyddsglasögon för kemikalier.

Hud/kropp Använd skyddskläsel

Begränsning av miljöexponeringen Följ praxis för hantering och avfallshantering.

Nyckeln till förkortningar
OSHA = Occupational Safety and Health Administration (Arbetsmiljöverket)
TWA = Genomsnittligt värde per tidsenhet är baserat på en exponering på 8h/dag, 40 h/ vecka

Avsnitt 9: Fysikaliska och kemiska egenskaper

9.1 Information om fysikaliska och kemiska egenskaper

Materialbeskrivning			
Fysisk form	Vätska	Färg	Färglös
Lukt	Luktlös	Lukttröskel	Data saknas
Allmänna egenskaper			
Kokpunkt	100 °C (212 °F)	Smältpunkt/fryspunkt	0 °C (32 °F)
Sönderdelningstemperatur	Data saknas	pH	3,3 till 8,8
Specifik vikt/relativ densitet	= 1 vatten=1	Löslighet i vatten	Löslig 100 %
Viskositet	Data saknas	Explosiva egenskaper	Data saknas
Oxiderande egenskaper:	Data saknas		
Volatilitet			
Ångtryck	Minimal	Ångdensitet	Data saknas
Avdunstningshastighet	Minimal		
Brandfarlighet			
Flampunkt	Data saknas	UEL	Data saknas
LEL	Data saknas	Självantändning	Data saknas
Brandfarlighet (fast, gas)	Data saknas		
Miljö			
Fördelningskoefficient oktanol/vatten	Data saknas		

9.2 Övriga Upplysningar

Inga ytterligare fysikaliska och kemiska egenskaper noterade.

Avsnitt 10: Stabilitet och reaktivitet

10.1 Reaktivitet

Inga farliga reaktioner kända under normala användningsvillkor.

10.2 Kemisk stabilitet

Stabil

10.3 Risken för farliga reaktioner

Farlig polymerisation uppstår inte.

10.4 Förhållanden som ska undvikas

Oförenliga material. Brinnande plastkassetter som innehåller reagens kan frigöra toxiska biprodukter.

10.5 Oförenliga material

Syror.

10.6 Farliga sönderdelningsprodukter

Brinnande plastkassetter som innehåller reagens kan frigöra toxiska biprodukter.

Avsnitt 11: Toxikologisk information

11.1 Information om toxikologiska effekter

Komponenter		
Guanidintiocyanat	593-84-0	**Akut toxicitet:** Intraperitoneal–mus LD50 • 593 mg/kg

GHS-egenskaper	Klassificering
Akut toxicitet	**EU/CLP**•Data saknas **FN GHS**•Akut toxicitet - Oral - Kategori 5 **OSHA HCS 2012**•Data saknas
Hudkänslighet /irritation	**EU/CLP**•Data saknas **FN GHS**•Mild hudirritation Kategori 3 **OSHA HCS 2012**•Data saknas
Allvarlig ögonskada/irritation	**EU/CLP**•Data saknas **FN GHS**•Mild ögonirritation Kategori 2B **OSHA HCS 2012**•Mild ögonirritation Kategori 2B
Hudsensibilisering	**EU/CLP**•Data saknas **FN GHS**•Data saknas **OSHA HCS 2012**•Data saknas
Respiratorisk överkänslighet	**EU/CLP**•Data saknas **FN GHS**•Data saknas **OSHA HCS 2012**•Data saknas
Cancerframkallande egenskaper	**EU/CLP**•Data saknas **FN GHS**•Data saknas **OSHA HCS 2012**•Data saknas

GHS-egenskaper	Klassificering
Könscellmutagenitet	**EU/CLP**•Data saknas **FN GHS**•Data saknas **OSHA HCS 2012**•Data saknas
Reproduktionsstörande	**EU/CLP**•Data saknas **FN GHS**•Data saknas **OSHA HCS 2012**•Data saknas
SPECIFIK ORGANTOXICITET-SE	**EU/CLP**•Data saknas **FN GHS**•Data saknas **OSHA HCS 2012**•Data saknas

Potentiella hälsoeffekter

Inandning
Akut (omedelbart) Kan orsaka irritation.
Kronisk (försenad) Inga data tillgängliga
Hud
Akut (omedelbart) Orsakar mild hudirritation.
Kronisk (försenad) Inga data tillgängliga
Ögon
Akut (omedelbart) Orsakar ögonirritation.
Kronisk (försenad) Inga data tillgängliga
Förtäring
Akut (omedelbart) Kan vara farligt vid förtäring.
Kronisk (försenad) Inga data tillgängliga

Nyckeln till förkortningar
LD = Dödlig dos

Avsnitt 12: Ekologisk information

12.1 Toxicitet

LC50 (guppy): 89,1 mg/l vid 96 h

12.2 Motståndskraft och nedbrytbarhet

Materialdata saknas.

12.3 Bioackumuleringsförmåga

Materialdata saknas.

12.4 Rörligheten i jord

Materialdata saknas.

12.5 Resultat av PBT- och vPvB-bedömningen

Ingen PBT och vPvB bedömning har gjorts.

12.6 Andra skadliga effekter

Inga studier har hittats.

Avsnitt 13: Avfallshantering

13.1 Metoder för behandling av avfall

Produktavfall Avyttra innehållet och /eller behållaren i enlighet med lokala, regionala, nationella och/ eller internationella förordningar.

Förpackningsavfall Avyttra innehållet och /eller behållaren i enlighet med lokala, regionala, nationella och/ eller internationella förordningar.

13.2 Övrig information

Biologiska prover, överföringsanordningar och använda kassetter bör anses kunna överföra smittämnen som kräver standardåtgärder. Följ din institutions rutiner för korrekt bortskaffande av använda kassetter och oanvända reagens. Dessa material kan uppvisa egenskaper som kemiskt farligt avfall som kräver specifika nationella eller regionala bortskaffningsförfaranden. Om nationella eller regionala föreskrifter inte ger tydliga riktlinjer för korrekt bortskaffande ska biologiska prover och använda kassetter kasseras enligt WHO:s (Världshälsoorganisationens) föreskrifter om hantering och bortskaffande av avfall.

Avsnitt 14: Transportinformation

	14.1 UN-nummer	14.2 UN lämpligt transportnamn	14.3 Transport riskklasser	14.4 Förpackningsgrupp	14.5 Miljöfaror
DOT	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämplig
TDG	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämplig
IMO/IMDG	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämplig
IATA/ICAO	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämplig

14.6 Särskilda försiktighetsåtgärder för användare

Inga specificerat.

14.7 Bulktransport enligt bilaga II MARPOL 73/78 och IBC-koden

Inte relevant.

Avsnitt 15: Gällande föreskrifter

15.1 Säkerhets-, hälso- och miljöföreskrifter/lagstiftning om ämnet eller blandningen

SARA Riskklassificeringar Akut

Inventering						
Komponent	**CAS**	**Kanada DSL**	**Kanadensiska NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidintiocyanat	593-84-0	Ja	Nej	Ja	Nej	Ja

Kanada

Arbete

Kanada - WHMIS - klassificeringar av ämnen

•Guanidintiocyanat 593-84-0 Inte listade

Kanada - WHMIS - lista på angivna ingredienser

•Guanidintiocyanat 593-84-0 Inte listade

Miljö

Kanada - CEPA - lista på prioriterade ämnen

•Guanidintiocyanat 593-84-0 Inte listade

USA

Arbete

USA - OSHA - Process Safety Management - mycket farliga kemikalier

•Guanidintiocyanat	593-84-0	Inte listade

U.S. - OSHA - särskilt reglerade kemikalier

•Guanidintiocyanat	593-84-0	Inte listade

Miljö

USA - CAA (Clean Air Act) - 1990 farliga luftföroreningar

•Guanidintiocyanat	593-84-0	Inte listade

USA - CERCLA/SARA - farliga ämnen och vilka kvantiteter som bör rapporteras

•Guanidintiocyanat	593-84-0	Inte listade

USA - CERCLA/SARA - radionuklider och de kvantiteter som rapporteras

•Guanidintiocyanat	593-84-0	Inte listade

USA - CERCLA/SARA - avsnitt 302 extremt farliga ämnen EPCRA RQs

•Guanidintiocyanat	593-84-0	Inte listade

USA - CERCLA/SARA - avsnitt 302 extremt farliga ämnen TPQs

•Guanidintiocyanat	593-84-0	Inte listade

USA - CERCLA/SARA - avsnitt 313 – utsläppsrapportering

•Guanidintiocyanat	593-84-0	Inte listade

USA - CERCLA/SARA - avsnitt 313 - PBT kemisk lista

•Guanidintiocyanat	593-84-0	Inte listade

USA - California

Miljö

USA - Kalifornien - Proposition 65 - lista på cancerframkallande ämnen

•Guanidintiocyanat	593-84-0	Inte listade

USA - Kalifornien - Proposition 65 – utvecklingstoxicitet

•Guanidintiocyanat	593-84-0	*Inte listade*

USA - Kalifornien - Proposition 65 - högsta tillåtna nivå på dos (MADL)

•Guanidintiocyanat	593-84-0	Inte listade

USA - Kalifornien - Proposition 65 - inga betydande risknivåer (NSRL)

•Guanidintiocyanat	593-84-0	Inte listade

USA - Kalifornien - Proposition 65 - reproduktiv toxicitet – kvinna

•Guanidintiocyanat	593-84-0	Inte listade

USA - Kalifornien - Proposition 65 - reproduktiv toxicitet - man

•Guanidintiocyanat	593-84-0	Inte listade

15.2 Kemikaliesäkerhetsbedömning

Ingen kemikaliesäkerhetsbedömning har genomförts.

Avsnitt 16: Annan information

Relevanta termer (kod & fulltext)

H302 – Skadligt vid förtäring.
H313 – Kan vara skadligt vid hudkontakt.
H320 – Orsakar ögonirritation.

Ansvarsfrihet/ Försäkran om ansvar

Ovanstående information är baserad på data tillgängliga för oss och anses vara korrekt. Eftersom informationen kan användas under förhållanden utanför vår kontroll och som är okänd för oss, kan vi inte ta något ansvar för resultatet av dess användning och alla personersom tar del av den måste göra en egen bedömning av effekter, egenskaper, skydd, ochavyttring som hänför sig till deras särskilda förhållanden. Ingen representation eller garanti,uttrycklig eller underförstådd (inklusive en garanti om lämplighet eller säljbarhet för ett visst ändamål), görs med avseende på material, riktigheten i denna information, de resultat som uppnås vid användning därav, eller de risker som är förknippade med användningen av materialet. Försiktighet skall iakttas vid hantering och användning av materialet. Ovanstående information ges i god tro ochmed tron att det är korrekt. Från och med dagen för utfärdandet, tillhandahåller vi all relevant informationför förutsägbar hantering av materialet. Men i händelse av en skadlig incidenti samband med denna produkt, är detta säkerhetsdatablad inte, och är inte avsedd att vara ett substitut för rådgivning med lämpligt utbildad personal.

Nyckeln till förkortningar
NDA = Inga data tillgängliga

Паспорт безопасности материала
Дата вступления в силу: Январь 2021 г.
Отменяет версию документа за: Сентябрь 2020 г.

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Раздел 1. Общие сведения о веществе веществе/смеси и производителе

1.1 Идентификатор продукта

Наименование продукта **Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**

Код продукта 900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Выявленные и нерекомендованные способы применения вещества или смеси

Выявленные способы применения Для использования в лабораторных условиях

1.3 Сведения об организации, предоставившей паспорт безопасности материала

Производитель Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States (США)
www.cepheid.com
US: techsupport@cepheid.com

Телефон (общий) 1 (888) 838-3222 - США, дополнит. 2

Телефон (общий) 1 (408) 541-4191 - За пределами США

Поставщик Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden (Швеция)
www.cepheidinternational.com
EU: support@cepheideurope.com

Телефон (общий) +33 563 825 319

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
Australia (Австралия)
www.cepheidinternational.com
Австралия и Новая Зеландия: TechSupportANZ@cepheid.com

Телефон (Австралия) 1800 107 884

1.4 Телефон для экстренной связи

Производитель 1 (800) 535-5053 - INFOTRAC - круглосуточный телефон экстренного вызова

Производитель 1 (352) 323-3500 - За пределами США

Раздел 2. Идентификация опасности

ЕС/ЕЭС

Согласно: Регламент ЕК (ЕС) № 1272/2008 (CLP)/REACH 1907/2006 [с поправками, внесенными директивой 453/2010]

2.1 Классификация вещества или смести

Регламент CLP

Следующий паспорт безопасности материала действителен только для готовой смеси, используемой в лабораторных условиях. Продукт содержит гранулы и реактивы в картридже или в отдельных контейнерах. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) регламента CLP и разделом 29 Свода федеральных правил (США), ст. 1910.1200(g)(2)(i)(C)(1) и (2).
Не классифицируется

2.2 Элементы маркировки

Регламент CLP

Указания на опасность

Маркировка не требуется.

2.3 Другие факторы опасности

Регламент CLP

Согласно Регламенту ЕК № 1272/2008 (CLP) этот материал не считается опасным.

СГС ООН (Содержание маркировки, указываемой на продукции)

Согласно: Согласованная на глобальном уровне система классификации опасности и маркировки химической продукции (СГС) ООН.

2.1 Классификация вещества или смести

СГС ООН

Острая токсичность, перорально, 5
Слабое раздражение кожи, 3
Слабое раздражение глаз, 2B

2.2 Элементы маркировки

СГС ООН

ВНИМАНИЕ!

Указания на опасность

Может быть вредно при проглатывании.
Может причинить вред при попадании на кожу.
Вызывает раздражение глаз.

Меры предосторожности

Профилактика

После использования тщательно вымыть руки.

Реагирование

При раздражении кожи: Обратиться за медицинской консультацией/помощью.
ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание.
При раздражении глаз: Обратиться за медицинской консультацией/помощью.
При плохом самочувствии обратиться в ТОКСИКОЛОГИЧЕСКИЙ ЦЕНТР или к врачу-специалисту/терапевту.

2.3 Другие факторы опасности

СГС ООН В соответствии с Согласованной на глобальном уровне системой классификации опасности и маркировки химической продукции (СГС) данный продукт считается опасным.

США
Согласно: OSHA 29 CFR 1910.1200 HCS

2.1 Классификация вещества или смести

OSHA HCS 2012 Слабое раздражение глаз, 2B

2.2 Элементы маркировки

OSHA HCS 2012

Указания на опасность Вредно при проглатывании.
Может причинить вред при попадании на кожу.
Вызывает раздражение глаз.

Меры предосторожности

Профилактика После использования тщательно вымыть руки.

Реагирование ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание.
При раздражении глаз: Обратиться за медицинской консультацией/помощью.

2.3 Другие факторы опасности

OSHA HCS 2012 Согласно государственным нормам США (документ 29 CFR 1910.1200 – Стандарт-требование об оповещении об опасности) этот продукт не считается опасным.

Канада
Согласно: WHMIS

2.1 Классификация вещества или смести

WHMIS Не классифицируется

2.2 Элементы маркировки

WHMIS Маркировка не требуется.

2.3 Другие факторы опасности

WHMIS В Канаде указанное выше вещество согласно требованиям Информационной системы по опасным материалам на рабочих местах (WHMIS) не считается опасным.

2.4 Дополнительная информация

Все остальные реактивы, гранулы и прочие составляющие представлены в смеси в концентрациях менее 1% или не считаются опасными согласно Стандартам-требованиям США об оповещении об опасности (29 CFR 1910.1200), директивам ЕС в отношении классификации и маркировки веществ и смесей и Согласованной на глобальном уровне системе классификации опасности и маркировки химической продукции (СГС).

Раздел 3. Состав/информация о компонентах

3.1 Вещества

Материал не отвечает критериям классификации, применяемым к веществам.

3.2 Смеси

Состав					
Химическое наименование	**Идентификаторы**	**%**	**LD50/LC50**	**Классификация в соответствии с нормами/ постановлениями**	**Комментарии**
Гуанидина тиоцианат	**CAS:** 593-84-0 **EINECS:** 209-812-1	10–20%	593 мг/кг	**EU CLP:** острая токсичность 5, H302, H313, H320 **СГС ООН:** острая токсичность 5 (перорально); раздражение кожи 3; раздражение глаз 2B **OSHA HCS 2012:** острая токсичность 5 (перорально); раздражение глаз 2B	Нет данных

Раздел 4. Первая медицинская помощь

4.1 Описание мер первой медицинской помощи

Вдыхание Первая помощь, вероятно, не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. Вынести пострадавшего на свежий воздух. При затрудненном дыхании дать кислород. Не применять искусственное дыхание рот-в-рот при вдыхании вещества. Делать искусственное дыхание с помощью маски с клапаном или другого медицинского устройства. При остановке дыхания сделать искусственное дыхание.

Кожа Первая помощь, вероятно, не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При незначительном контакте с кожей избегайте распространения материала на незатронутые участки. В случае контакта вещества с кожей незамедлительно промыть пораженный участок проточной водой в течение не менее чем 20 минут. Снять и изолировать загрязненную одежду.

Глаза Первая помощь, вероятно, не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. В случае контакта вещества с кожей незамедлительно промыть глаза проточной водой в течение не менее чем 20 минут. При раздражении глаз: Обратиться за медицинской консультацией/помощью.

Проглатывание Первая помощь, вероятно, не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При проглатывании прополоскать рот водой (только если человек находится в сознании). НЕ вызывать рвоту. Не применять искусственное дыхание рот-в-рот при проглатывании вещества. При попадании материала внутрь сразу же обратиться к врачу.

4.2 Наиболее важные остро выраженные и проявляющиеся с задержкой симптомы и последствия

См. раздел 11, «Токсикологическая информация».

4.3 Признаки необходимости неотложной медицинской помощи и специального ухода

Примечания для врача	Лечение основывать на наблюдаемых симптомах. Учитывать возможность одновременного воздействия на пациента и других веществ.

Раздел 5. Меры противопожарной безопасности

5.1 Средства пожаротушения

Подходящие средства пожаротушения	КРУПНЫЕ ПОЖАРЫ. Порошок, углекислый газ (CO2), спиртоустойчивые пенообразователи, разбрызгивание воды. НЕБОЛЬШОЙ ПОЖАР. Сухой химический огнетушитель, углекислый газ (CO2), разбрызгивание воды.
Непригодные средства пожаротушения	Данные отсутствуют

5.2 Особые аспекты опасности вещества или смести

Особая огне- и взрывоопасность	Пластмассовый картридж содержит реактивы, способные выделять токсичные испарения: оксиды углерода, оксиды серы, оксиды азота.
Опасные продукты горения	Данные отсутствуют

5.3 Рекомендации по пожаротушению

Защитная одежда пожарных для тушения пожаров в зданиях обеспечивает ограниченную защиту ТОЛЬКО в условиях пожара; она не является эффективным средством защиты при разливах с возможным непосредственным контактом с веществами.
Носить химическую защитную одежду, рекомендованную производителем. Она малоэффективна или неэффективна в качестве тепловой защиты.
Использовать автономные дыхательные аппараты.
НЕБОЛЬШОЙ ПОЖАР. Уберите контейнеры из зоны пожара, если можете сделать это без риска.

Раздел 6. Меры при выбросе

6.1 Меры по обеспечению личной безопасности, средства защиты и действия в чрезвычайной ситуации

Меры по обеспечению личной безопасности	В случае разбития картриджа актуальны указанные меры по обеспечению личной безопасности. Используйте соответствующую защитную одежду. Не ходите по разлитому/просыпанному материалу. Не прикасайтесь к поврежденным контейнерам или разлитым материалам, если нет соответствующей защитной одежды. Проветривайте закрытые помещения.
Действия в чрезвычайных ситуациях	Вероятно, экстренные меры не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций.

6.2 Охрана окружающей среды

Не допускать попадания в водоемы, канализацию, подвалы и замкнутые пространства.

6.3 Методы и средства локализации и очистки

Меры по локализации и очистке	При небольших разливах используйте перчатки. Для сбора вещества используйте бумажные полотенца. Не сливать пролитые вещества в канализацию.

6.4 Ссылки на другие разделы

См. раздел 8, «Меры контроля воздействия и средства индивидуальной защиты», и раздел 13, «Условия утилизации».

Раздел 7. Правила обращения и хранения

7.1 Инструкция по безопасному обращению с продуктом

Обращение Особое обращение не требуется. В случае разбития картриджа избегайте контакта с разлившимся реактивом. Избегать контакта с кожей и глазами.

7.2 Условия безопасного хранения и учет факторов несовместимости

Место хранения Хранить согласно указаниям на упаковке. Хранить вдали от несовместимых материалов. Хранить под замком. Хранить контейнер/упаковку плотно закрытыми в прохладном, хорошо проветриваемом месте.

7.3 Особые способы применения

См. раздел 1.2, «Выявленные и способы применения».

Раздел 8. Меры контроля воздействия и индивидуальные средства защиты

8.1 Контрольные параметры

	Предельно допустимые концентрации/рекомендации			
	Результат	**ACGIH**	**NIOSH**	**OSHA**
Гуанидинтиоцианат	TWA	Не установлено	Не установлено	Не установлено

8.2 Меры и средства контроля воздействия

Инженерно-технические мероприятия/средства контроля Желательно обеспечить хорошую вентиляцию. Интенсивность вентиляции должна соответствовать условиям хранения/использования. Если возможно, используйте ограниченные рабочие помещения, местную вытяжную вентиляцию и прочие средства для сдерживания концентрации вещества в воздухе на уровне ниже ПДК. Если ПДК не установлены поддерживайте приемлемые концентрации вещества в воздухе.

Индивидуальные средства защиты

Защита органов дыхания Ожидается, что средства защиты органов дыхания не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций. В противном случае соблюдайте рекомендации по использованию респираторов Управления охраны труда (OSHA) США, изложенные в документе 29 CFR 1910.134, или Европейского стандарта EN 149. При превышении ПДК или обнаружении признаков поражения используйте респираторы, одобренные Национальным институтом по безопасности и гигиене труда (США), Управлением по безопасности и охране труда в добывающей промышленности (США) или Европейским стандартом EN 149.

Защита глаз/лица Носите очки химической защиты.

Защита кожных покровов/тела Используйте защитную одежду.

Защита окружающей среды Соблюдайте общие правила работы на объекте и удаления отходов.

Сокращения
OSHA = Управление охраны труда, США (Occupational Safety and Health Administration).
TWA = Средневзвешенная во времени концентрация, вычисляемая на основании воздействия в течение 8 часов в день, 40 часов в неделю.

Раздел 9. Физические и химические свойства

9.1 Информация о физических и химических свойствах

Описание материала			
Физическая форма	Жидкость	Цвет	Бесцветное
Запах	Без запаха	Порог ощущения запаха	Данные отсутствуют
Общие свойства			
Точка кипения	100 °C (212 °F)	Температура плавления/замерзания	0 °C (32 °F)
Температура разложения	Данные отсутствуют	pH	от 3,3 до 8,8
Удельный вес/относительная плотность	= 1 вода=1	Растворимость в воде	Растворимо 100%
Вязкость	Данные отсутствуют	Взрывчатые свойства	Данные отсутствуют
Окислительные свойства:	Данные отсутствуют		
Летучесть			
Давление паров	Мин.	Плотность паров	Данные отсутствуют
Интенсивность испарения	Мин.		
Воспламеняемость			
Температура вспышки	Данные отсутствуют	ВКПВ (верхний предел взрывоопасности)	Данные отсутствуют
НПВ (нижний предел взрывоопасности)	Данные отсутствуют	Самовоспламенение	Данные отсутствуют
Воспламеняемость (в твердом, газообразном состоянии)	Данные отсутствуют		
Экологическая			
Коэффициент разделения октанол/вода	Данные отсутствуют		

9.2 Дополнительная информация

Дополнительные физические и химические свойства не обнаружены.

Раздел 10. Стабильность и химическая активность

10.1 Реакционная способность

В нормальных условиях использования опасные реакции неизвестны.

10.2 Химическая стабильность

Стабильно

10.3 Вероятность опасных реакций

Опасная полимеризация не происходит.

10.4 Недопустимые условия

Несовместимые материалы. При сжигании пластмассового картриджа, содержащего реактивы, могут высвобождаться токсические вещества.

10.5 Несовместимые материалы

Кислоты.

10.6 Опасные продукты разложения

При сжигании пластмассового картриджа, содержащего реактивы, могут высвобождаться токсические вещества.

Раздел 11. Токсикологическая информация

11.1 Информации о токсикологических последствиях

Компоненты		
Гуанидинтиоцианат	593-84-0	**Острая токсичность:** внутрибрюшинный-мышь LD50 • 593 мг/кг

Свойства (СГС)	Классификация
Токсичность при кратковременном воздействии	**EU/CLP**•Данные отсутствуют **СГС ООН**•Токсичность при кратковременном воздействии – орально - Категория 5 **OSHA HCS 2012**•Данные отсутствуют
Поражающее/раздражающее воздействие на кожу	**EU/CLP**•Данные отсутствуют **СГС ООН** •Слабое раздражение кожиКатегория 3 **OSHA HCS 2012**•Данные отсутствуют
Серьезные повреждения/раздражание глаз	**EU/CLP**•Данные отсутствуют **СГС ООН**•Слабое раздражение глазКатегория 2B **OSHA HCS 2012**•Слабое раздражение глазКатегория 2B
Сенсибилизация кожи	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Сенсибилизация органов дыхания	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Канцерогенность	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Мутагенность для зародышевых клеток	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Токсическое действие на репродуктивную функцию	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Органоспецифическая токсичность при однократном воздействии (STOT-SE)	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют

Возможные последствия для здоровья

Вдыхание
Остро выраженные последствия Может вызвать раздражение.
Хронические последствия Данные отсутствуют
Кожа
Остро выраженные последствия Вызывает легкое раздражение кожи.
Хронические последствия Данные отсутствуют
Глаза
Остро выраженные последствия Вызывает раздражение глаз.
Хронические последствия Данные отсутствуют
Проглатывание
Остро выраженные последствия Может быть вредно при проглатывании.
Хронические последствия Данные отсутствуют

Сокращения
LD = Летальная доза

Раздел 12. Экологическая информация

12.1 Токсичность

LC50 (гуппи): 89,1 мг/л за 96 ч

12.2 Устойчивость и склонность к разложению

Данные о материале отсутствуют.

12.3 Способность к биоаккумуляции

Данные о материале отсутствуют.

12.4 Подвижность в почве

Данные о материале отсутствуют.

12.5 Классификация как «устойчивое биоаккумулятивное токсическое вещество» и «очень устойчивое биоаккумулятивное вещество»

Оценка соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества» не производилась.

12.6 Другие неблагоприятные последствия

Исследования не проводились.

Раздел 13. Условия утилизации

13.1 Методы переработки отходов

Отходы продукта	Утилизация тары и/или содержимого должна осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.
Отходы упаковки	Утилизация тары и/или содержимого должна осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

13.2 Дополнительная информация

Биологические образцы, устройства для переноса и использованные картриджи следует считать возможными переносчиками возбудителей инфекционных заболеваний, и они требуют соблюдения стандартных мер предосторожности. Для правильного удаления в отходы использованных картриджей и неиспользованных реактивов следуйте принятым в вашем учреждении правилам защиты окружающей среды. Эти материалы могут иметь свойства химически опасных отходов и требовать выполнения особых национальных или региональных процедур удаления в отходы. Если принятые в стране или регионе правила не дают ясных указаний по правильному удалению в отходы, биологические образцы и использованные картриджи следует удалять в отходы с соблюдением правил ВОЗ (Всемирной организации здравоохранения) относительно обращения с медицинскими отходами и их удаления.

Паспорт безопасности материала
Дата вступления в силу: Январь 2021 г.
Отменяет версию документа за: Сентябрь 2020 г.

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2 Xpert Xpress SARS-CoV-2/Flu/RSV

Канада

Труд

Канада — Информационная система по опасным материалам на рабочих местах (WHMIS) — Классификация веществ

•Гуанидинтиоцианат	593-84-0	Не числится

Канада — Информационная система по опасным материалам на рабочих местах (WHMIS) — Список обязательных к раскрытию ингредиентов

•Гуанидинтиоцианат	593-84-0	Не числится

Окружающая среда

Канада — CEPA — Список приоритетных веществ

•Гуанидинтиоцианат	593-84-0	Не числится

США

Труд

США — Управление охраны труда — Обеспечение безопасности производственного процесса — Высокоопасные химикаты

•Гуанидинтиоцианат	593-84-0	Не числится

США — Управление охраны труда — Химические вещества с установленными нормативами

•Гуанидинтиоцианат	593-84-0	Не числится

Окружающая среда

США — Закон о чистом воздухе, 1990 — Опасные загрязняющие воздух вещества

•Гуанидинтиоцианат	593-84-0	Не числится

США — Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон США о воздействии на окружающую среду, компенсациях и ответственности (SARA) — Опасные вещества и обязательные для декларирования количества

•Гуанидинтиоцианат	593-84-0	Не числится

США — Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон США о воздействии на окружающую среду, компенсациях и ответственности (SARA) — Радионуклиды и обязательные для декларирования количества

•Гуанидинтиоцианат	593-84-0	Не числится

США — Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон США о воздействии на окружающую среду, компенсациях и ответственности (SARA) — Радионуклиды и обязательные для декларирования количества — Раздел 302. Чрезвычайно опасные вещества. Планирование скорой помощи и право общества на информацию. Относительные количества

•Гуанидинтиоцианат	593-84-0	Не числится

США — Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон США о воздействии на окружающую среду, компенсациях и ответственности (SARA) — Радионуклиды и обязательные для декларирования количества — Раздел 302. Чрезвычайно опасные вещества. Планирование скорой помощи и право общества на информацию. Пороговые количества

•Гуанидинтиоцианат	593-84-0	Не числится

США — Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон США о воздействии на окружающую среду, компенсациях и ответственности (SARA) — Радионуклиды и обязательные для декларирования количества — Раздел 313. Оповещение о выбросах

•Гуанидинтиоцианат	593-84-0	Не числится

США — Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон США о воздействии на окружающую среду, компенсациях и ответственности (SARA) — Радионуклиды и обязательные для декларирования количества — Раздел 313. Список устойчивых биоаккумулятивных токсических веществ

•Гуанидинтиоцианат	593-84-0	Не числится

США — Калифорния

Окружающая среда

США — Калифорния — Предложение 65 — Список канцерогенов		
•Гуанидинтиоцианат	593-84-0	Не числится
США — Калифорния — Предложение 65 — Эмбриотоксичность		
•Гуанидинтиоцианат	593-84-0	*Не числится*
США — Калифорния — Предложение 65 — Предельно допустимые дозы		
•Гуанидинтиоцианат	593-84-0	Не числится
США — Калифорния — Предложение 65 — Условно безопасные концентрации		
•Гуанидинтиоцианат	593-84-0	Не числится
США — Калифорния — Предложение 65 — Влияние на женский организм		
•Гуанидинтиоцианат	593-84-0	Не числится
США — Калифорния — Предложение 65 — Влияние на мужской организм		
•Гуанидинтиоцианат	593-84-0	Не числится

15.2 Оценка химической безопасности

Оценка химической безопасности не проводилась.

Раздел 16. Прочая информация

Фразы-предостережения (код и текст)

H302 – Вредно при проглатывании.
H313 – Может причинить вред при попадании на кожу.
H320 – Вызывает раздражение глаз.

Отказ от ответственности/ ограничение ответственности

Представленные выше сведения основаны на доступных нам данных и считаются верными. В связи с тем, что представленная информация может быть использована в не зависящих от нас и неизвестных нам условиях, мы не несем ответственность за последствия ее использования, а все лица, получающие эту информацию, должны самостоятельно принимать решения относительно последствий применения, свойств, средств защиты и способов утилизации вещества в соответствии с конкретными условиями применения. Мы не заявляем, не даем каких-либо гарантий и поручительств, будь то явных или подразумеваемых (включая гарантии пригодности или товарной ценности для конкретной цели), в отношении материалов и точности информации, полученных при их использовании результатов, а также опасностях, связанных с использованием данного материала. При взаимодействии с материалом и его использовании следует проявлять осторожность. Представленная выше информация передана добросовестно с уверенностью в ее точности. Мы предоставляем всю информацию, касающуюся предполагаемого использования материала, по состоянию на момент публикации. Однако в случае нежелательных последствий, связанных с данным продуктом, настоящий Паспорт безопасности материала не является и не может являться заменой консультации с соответствующим специалистом.

Сокращения
NDA = Данные отсутствуют

Паспорт із безпеки продукту
Дата набрання чинності: Січень 2021 р.
Заміняє версію документу від: Вересень 2020 р.

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

Розділ 1: Загальні відомості про речовину/суміш та компанію/виробника

1.1 Ідентифікатор продукту

Назва продукту **Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**

Код продукту 900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 Рекомендовані і не рекомендовані способи використання речовини або суміші

Рекомендовані способи використання Для використання в лабораторних умовах

1.3 Інформація про організацію, що надала паспорт з безпеки продукту

Виробник
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Сполучені Штати Америки
www.cepheid.com
США: techsupport@cepheid.com

Телефон (загальний) 1 (888) 838-3222 - США варіант 2

Телефон (загальний) 1 (408) 541-4191 - За межами США

Постачальник
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Швеція
www.cepheidinternational.com
ЄС: support@cepheideurope.com

Телефон (загальний) +33 563 825 319

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
Австралія
www.cepheidinternational.com
Австралія і Нова Зеландія: TechSupportANZ@cepheid.com

Телефон (Австралія) 1800 107 884

1.4 Номер телефону для надзвичайних ситуацій

Виробник 1 (800) 535-5053 - INFOTRAC - цілодобово для надзвичайних ситуацій

Виробник 1 (703) 741-5500 - За межами США

Розділ 2: Визначення небезпеки

ЄС/ЄЄС

Відповідно до: Регламенту (ЄС) № 1272/2008 (CLP)/REACH 1907/2006 [з поправками, внесеними постановою 453/2010]

2.1 Класифікація речовини або суміші

Регламент CLP

Цей паспорт з безпеки продукту дійсний лише для готової суміші, яка використовується в лабораторних умовах. У складі продукту містяться гранули та реактиви в картриджі або в окремих контейнерах. Винятки щодо розкриття інформації щодо деяких компонентів відповідають вимогам Статті 1(5)(d) Регламенту CLP і розділу 29 Кодексу Федеральних правил (CFR) США 1910.1200(g)(2)(i)(C)(1)та(2).
Не класифікується

2.2 Елементи маркування

Регламент CLP

Повідомлення про небезпеку

Наявність елементів етикетки не обов'язкова.

2.3 Інші фактори небезпеки

Регламент CLP

Згідно з Постановою (ЄС) № 1272/2008 (CLP), цей матеріал не вважається небезпечним.

ГУС ООН (зміст етикеток, наявних на продукції)

Відповідно до: Глобально узгодженої в рамках ООН системи класифікації небезпеки і маркування хімічної продукції (ГУС)

2.1 Класифікація речовини або суміші

ГУС ООН

Гостра токсичність, перорально 5
Незначне подразнення шкіри 3
Незначне подразнення очей 2B

2.2 Елементи маркування

ГУС ООН

ЗАСТЕРЕЖЕННЯ

Повідомлення про небезпеку

шкідливий при ковтанні
Може завдати шкоди в разі контакту зі шкірою
Викликає подразнення очей

Вказівки щодо безпеки

Профілактика

Після роботи потрібно ретельно вимити руки.

Заходи реагування

У разі подразнення шкіри: Звернутися за медичною консультацією або по допомогу.
У РАЗІ ПОТРАПЛЯННЯ В ОЧІ: Обережно промийте водою протягом кількох хвилин. Зняти контактні лінзи, якщо вони є та якщо це легко зробити. Продовжити промивання.
Якщо подразнення очей не проходить: Звернутися за медичною консультацією або по допомогу.
У разі поганого самопочуття звернутися в ТОКСИКОЛОГІЧНИЙ ЦЕНТР або до лікаря-фахівця чи терапевта.

2.3 Інші фактори небезпеки

ГУС ООН Відповідно до Глобально узгодженої системи класифікації небезпеки і маркування хімічної продукції (ГУС), даний продукт вважається небезпечним.

Сполучені Штати (США)
Відповідно до: OSHA 29 CFR 1910.1200 HCS

2.1 Класифікація речовини або суміші

OSHA HCS 2012 Незначне подразнення очей 2B

2.2 Елементи маркування

OSHA HCS 2012

Повідомлення про небезпеку
Шкідливо в разі ковтання
Може завдати шкоди в разі контакту зі шкірою
Викликає подразнення очей

Вказівки щодо безпеки

Профілактика Після роботи потрібно ретельно вимити руки.

Заходи реагування У РАЗІ ПОТРАПЛЯННЯ В ОЧІ: Обережно промийте водою протягом кількох хвилин. Зняти контактні лінзи, якщо вони є та якщо це легко зробити. Продовжити промивання.
Якщо подразнення очей не проходить: Звернутися за медичною консультацією або по допомогу.

2.3 Інші фактори небезпеки

OSHA HCS 2012 Відповідно до державних норм США (29 CFR 1910.1200 - Стандарт інформування про небезпечні речовини), цей продукт не вважається небезпечним.

Канада
Відповідно до: WHMIS

2.1 Класифікація речовини або суміші

WHMIS Не класифікується

2.2 Елементи маркування

WHMIS Наявність елементів етикетки не обов'язкова.

2.3 Інші фактори небезпеки

WHMIS У Канаді згаданий вище продукт не вважається небезпечним згідно з Інформаційною системою небезпечних матеріалів на робочому місці (WHMIS).

2.4 Додаткова інформація

Всі інші реактиви, гранули та інші складові представлені в суміші в концентраціях менше 1 % або не вважаються небезпечними згідно зі Стандартами США щодо сповіщення про небезпеку (29 CFR 1910.1200), директивами ЄС щодо класифікації та маркування речовин і сумішей і Глобальної узгодженої системи класифікації небезпеки та маркування речовин або сумішей.

Розділ 3: Склад/Інформація про компоненти

3.1 Речовини

Матеріал не відповідає критеріям речовини.

3.2 Суміші

Склад					
Хімічне найменування	**Ідентифікатори**	**%**	**LD50/LC50**	**Класифікація відповідно до Норм/Директиви**	**Коментарі**
Гуанідинтіоціанат	**CAS:** 593-84-0 **EINECS:** 209-812-1	10 %-20 %	593 мг/кг	**ЄС CLP:** Гостра токсичність 5, H302, H313, H320 **ГУС ООН:** Гостра токсичність 5 (перорально); Подразнення шкіри 3; Подразнення очей 2B **OSHA HCS 2012:** Гостра токсичність 5 (перорально); Подразнення очей 2B	NDA

Розділ 4: Заходи першої медичної допомоги

4.1 Опис заходів першої медичної допомоги

Вдихання

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. Винести потерпілого на свіже повітря. При утрудненому диханні дати кисень. При вдиханні речовини не застосовувати штучне дихання рот-в-рот. Виконати штучне дихання за допомогою кишенькової маски з клапаном односторонньої дії або іншого відповідного медичного пристрою. При зупинці дихання забезпечити штучне дихання.

Шкіра

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. При незначному контакті зі шкірою уникайте поширення матеріалу на непошкоджені ділянки. У разі контакту речовини зі шкірою негайно промити уражену ділянку проточною водою протягом не менше ніж 20 хвилин. Зняти та ізолювати забруднений одяг.

Очі

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. У разі потрапляння речовини негайно промити очі проточною водою протягом не менше ніж 20 хвилин. Якщо подразнення очей не проходить: Звернутися за медичною консультацією або по допомогу.

Ковтання

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. При ковтанні прополоскати рот водою (тільки якщо людина знаходиться в свідомості). НЕ викликати блювоту. Не застосовувати штучне дихання рот-в-рот при ковтанні речовини. При ковтанні матеріалу негайно звернутися до лікаря.

4.2 Найважливіші симптоми та наслідки, гострі та ті, що проявляються з затримкою

Див. Розділ 11 - Токсикологічна інформація.

4.3 Признаки необхідної невідкладної медичної допомоги та спеціального лікування

Примітки для лікаря

Всі методи лікування повинні грунтуватися на ознаках та симптомах тривоги, що спостерігаються у пацієнта. Слід враховувати можливість одночасного надмірного впливу на пацієнта й інших речовин, окрім даного продукту.

Розділ 5: Заходи протипожежної безпеки

5.1 Засоби гасіння пожежі

Придатні засоби гасіння пожежі	ВЕЛИКІ ПОЖЕЖІ: Сухий хімічний вогнегасний засіб, вуглекислий газ (CO2), спиртостійкі піноутворювачі або водяний спрей. НЕВЕЛИКІ ПОЖЕЖІ: Сухий хімічний вогнегасний засіб, вуглекислий газ (CO2) або водяний спрей.
Непридатні засоби гасіння пожежі	Дані відсутні

5.2 Особливі аспекти небезпеки, що виникають від речовини або суміші

Незвичайна вогненебезпека та вибухонебезпека	Пластмасовий картридж містить реактиви, здатні виділяти токсичні випари: оксиди вуглецю, оксиди сірки, оксиди азоту.
Небезпечні продукти горіння	Дані відсутні

5.3 Поради для пожежників

Захисний одяг пожежників для гасіння пожеж в будівлях забезпечує обмежений захист ТІЛЬКИ в умовах пожежі; він не є ефективним засобом захисту при розливах з можливим безпосереднім контактом з речовинами.
Носити одяг для хімічного захисту, спеціально рекомендований виробником. Він може бути малоефективний або неефективний в якості теплового захисту.
Використовувати автономні дихальні апарати, що працюють в режимі позитивного тиску (SCBA).
НЕВЕЛИКІ ПОЖЕЖІ: Заберіть контейнери із зони пожежі, якщо можете зробити це без ризику.

Розділ 6: Заходи щодо наслідків випадкового викиду матеріалу

6.1 Заходи щодо забезпечення особистої безпеки, засоби захисту та дії при надзвичайній ситуації

Заходи щодо забезпечення особистої безпеки	У разі розбиття картриджа актуальні зазначені заходи щодо забезпечення особистої безпеки. Використовуйте відповідний захисний одяг. Не ходіть по розлитому матеріалу. Не торкайтеся пошкоджених контейнерів або розлитого матеріалу, якщо немає відповідного захисного одягу. Провітріть закриті приміщення.
Дії при надзвичайній ситуації	Очікується, що заходи при надзвичайних ситуаціях не будуть потрібні, якщо матеріал використовується в звичайних умовах і з дотриманням рекомендацій.

6.2 Заходи щодо забезпечення безпеки навколишнього середовища

Не допускати викидання у водостоки, каналізацію, підвали і замкнутий простір.

6.3 Методи і засоби локалізації і очищення

Засоби локалізації і очищення	При невеликих розливах використовуйте рукавички. Для збору речовини використовуйте паперові рушники. Не зливати пролиті речовини в каналізацію.

6.4 Посилання на інші розділи

Див. Розділ 8 - Заходи контролю впливу та засоби індивідуального захисту, і розділ 13 - Умови утилізації.

Розділ 7: Правила поводження та зберігання

7.1 Запобіжні заходи при поводженні з продуктом

Поводження Не потребує особливого поводження. У разі розбиття картриджа уникайте контакту з розлитими реактивами. Уникати контакту зі шкірою та очима.

7.2 Умови безпечного зберігання, враховуючи всі фактори несумісності

Зберігання Зберігати відповідно до вказівок на упаковці. Тримати подалі від несумісних матеріалів. Зберігати під замком. Зберігати в щільно закритому контейнері/упаковці в прохолодному, добре провітрюваному місці.

7.3 Особливі способи застосування

Див. Розділ 1.2 - Рекомендовані способи застосування.

Розділ 8: Заходи контролю впливу та засоби індивідуального захисту

8.1 Параметри контролю

	Гранично допустимі концентрації/рекомендації			
	Результат	**ACGIH**	**NIOSH**	**OSHA**
Гуанідинтіоціанат	TWA	Не визначався	Не визначався	Не визначався

8.2 Заходи контролю впливу

Інженерно-технічні заходи/засоби контролю Необхідно забезпечити добру загальну вентиляцію. Інтенсивність вентиляції повинна відповідати умовам. Якщо можливо, використовуйте ізольований робочий простір, місцеву витяжну вентиляцію та інші інженерно-технічні засоби для підтримання концентрації речовини в повітрі на рівні нижче максимально допустимої концентрації. Якщо рівень максимально допустимої концентрації не встановлено, підтримуйте прийнятні концентрації речовини в повітрі.

Індивідуальні засоби захисту

Захист органів дихання Очікується, що засоби захисту органів дихання не будуть потрібні, якщо матеріал використовується в звичайних умовах і з дотриманням рекомендацій. В іншому випадку дотримуйтесь рекомендацій по використанню респіраторів Управління охорони праці (OSHA) США, викладених в документі 29 CPP 1910.134, або Європейського стандарту EN 149. При перевищенні максимально допустимої концентрації або виявленні ознак ураження використовуйте респіратори, схвалені Національним інститутом з безпеки та гігієни праці (NIOSH) США, Управлінням з безпеки і охорони праці у видобувній промисловості (MSHA) США або Європейським стандартом EN 149.

Захист очей/обличчя Одягайте окуляри хімічного захисту.

Захист шкіри/тіла Одягайте захисний одяг

Захист навколишнього середовища Дотримуйтесь загальних рекомендацій роботи на об'єкті та утилізації відходів.

Скорочення
OSHA = Управління охорони праці, США
TWA = Середньозважена в часі концентрація, що обчислюється на основі впливу протягом 8 годин в день, 40 годин на тиждень.

Розділ 9: Фізичні та хімічні властивості

9.1 Інформація про фізичні та хімічні властивості

Опис матеріалу			
Фізична форма	Рідина	Колір	Безбарвний
Запах	Без запаху	Поріг відчуття запаху	Дані відсутні
Загальні властивості			
Точка кипіння	100 °C (212 °F)	Температура плавлення/замерзання	0 °C (32 °F)
Температура розпаду	Дані відсутні	pH	3,3–8,8
Питома вага/відносна щільність	= 1 вода =1	Розчинність у воді	100 % розчинність
В'язкість	Дані відсутні	Вибухові властивості	Дані відсутні
Окислювальні властивості:	Дані відсутні		
Волатильність			
Тиск парів	Мінімальний	Щільність парів	Дані відсутні
Швидкість випаровування	Мінімальний		
Вогненебезпечність			
Температура займання	Дані відсутні	ВМВ (Верхня межа вибуховості)	Дані відсутні
НМВ (Нижня межа вибуховості)	Дані відсутні	Самозаймання	Дані відсутні
Вогненебезпечність (в твердому, газоподібному стані)	Дані відсутні		
В навколишньому середовищі			
Коефіцієнт розподілення октанол/вода	Дані відсутні		

9.2 Додаткова інформація

Додаткові фізичні та хімічні властивості не виявлені.

Розділ 10: Стабільність і реакційна здатність

10.1 Реакційна здатність

В нормальних умовах використання небезпечні реакції невідомі.

10.2 Хімічна стабільність

Стабільно

10.3 Імовірність небезпечних реакцій

Небезпечна полімеризація не відбувається.

10.4 Умови, яких слід уникати

Несумісні матеріали. При спалюванні пластмасового картриджа, що містить реактиви, можуть вивільнятися токсичні побічні речовини

10.5 Несумісні матеріали

Кислоти.

10.6 Небезпечні продукти розкладання

При спалюванні пластмасового картриджа, що містить реактиви, можуть вивільнятися токсичні побічні речовини.

Розділ 11: Токсикологічна інформація

11.1 Інформація про токсикологічні наслідки

Компонент		
Гуанідинтіоціанат	593-84-0	**Гостра токсичність:** Внутрішньоочеревно-миші LD50 • 593 мг/кг

Властивості (ГУС)	Класифікація
Гостра токсичність	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Гостра токсичність — перорально 5 **OSHA HCS 2012**•Дані відсутні
Роз'їдаюча/подразнююча дія на шкіру	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Незначне подразнення шкіри 3 **OSHA HCS 2012**•Дані відсутні
Серйозні пошкодження/подразнення очей	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Незначне подразнення очей 2B **OSHA HCS 2012**•Незначне подразнення очей 2B
Сенсибілізація шкіри	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Сенсибілізація органів дихання	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Канцерогенність	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Мутагенність для зародкових клітин	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Токсична дія на репродуктивну функцію	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Органоспецифічна токсичність при одноразовому впливі (STOT-SE)	**ЄС/CLP**•Дані відсутні **ГУС ООН**•Дані відсутні **OSHA HCS 2012**•Дані відсутні

Можливі наслідки для здоров'я

Вдихання
Гострі наслідки Можуть викликати подразнення.
Хронічні наслідки Дані відсутні
Шкіра
Гострі наслідки Можуть викликати незначне подразнення шкіри.
Хронічні наслідки Дані відсутні
Очі
Гострі наслідки Викликає подразнення очей.
Хронічні наслідки Дані відсутні
Ковтання
Гострі наслідки Може бути шкідливим у разі проковтування.
Хронічні наслідки Дані відсутні

Скорочення
LD = летальна доза

Розділ 12: Інформація про вплив на навколишнє середовище

12.1 Токсичність

LC50 (лабораторні рибки): 89,1 мг/л @ 96 год.

12.2 Стійкість і здатність до розкладання

Дані про матеріал відсутні.

12.3 Здатність до біоакумуляції

Дані про матеріал відсутні.

12.4 Рухливість в грунті

Дані про матеріал відсутні.

12.5 Результати оцінки відповідності ознакам «сталої біоакумулятивної токсичної речовини» і «дуже стійкої біоакумулятивної речовини»

Оцінка відповідності ознакам «сталої біоакумулятивної токсичної речовини» і «дуже стійкої біоакумулятивної речовини» не проводилася.

12.6 Інші небажані наслідки

Дослідження не проводились.

Розділ 13: Умови утилізації

13.1 Методи утилізації відходів

Відходи продукту Утилізацію вмісту та (або) контейнера необхідно здійснювати відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

Відходи упаковки Утилізацію вмісту та (або) контейнера необхідно здійснювати відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

13.2 Додаткова інформація

Біологічні зразки, пристрої для переносу та використані картриджі слід вважати можливими переносниками збудників інфекційних захворювань, які вимагають дотримання стандартних запобіжних заходів. Для правильної утилізації використаних картриджів і невикористаних реактивів дотримуйтеся прийнятих у вашому закладі правил захисту довкілля. Ці матеріали можуть мати властивості хімічно небезпечних відходів і вимагати виконання особливих державних або регіональних процедур для їх утилізації. Якщо прийняті в країні або регіоні правила не дають ясних указівок щодо правильної утилізації цих відходів, біологічні зразки та використані картриджі слід утилізувати з дотриманням правил ВООЗ (Всесвітньої організації охорони здоров'я) щодо поводження з медичними відходами та їх утилізації.

Розділ 14: Інформація щодо транспортування

	14.1 Номер ООН	14.2 Вантажне найменування ООН	14.3 Клас(и) небезпеки при транспортуванні	14.4 Група упаковки	14.5 Небезпека для навколишнього середовища
DOT	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується
TDG	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується
IMO/IMDG	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується
IATA/ICAO	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується

Раздел 14. Информация о транспортировке

	14.1 Номер ООН	14.2 Отгрузочное наименование ООН	14.3 Классы опасности при транспортировке	14.4 Группа упаковки	14.5 Экологическая опасность
DOT	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо
TDG	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо
IMO/IMDG	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо
IATA/ICAO	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо

14.6 Специальные меры предосторожности для пользователей

Не указаны.

14.7 Бестарная транспортировка в соответствии с Приложением II МАРПОЛ 73/78 и Кодексом IBC

Неприменимо

Раздел 15. Нормативная информация

15.1 Правовые акты в сфере безопасности, защиты здоровья и окружающей среды/особые правовые акты, применимые к веществу или смеси

Класс опасности (SARA) Острый

Запасы						
Component	**CAS**	**Канада, DSL**	**Канада, NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Гуанидинтиоцианат	593-84-0	Да	Нет	Да	Нет	Да

14.6 Спеціальні заходи безпеки для користувачів

Не вказано.

14.7 Транспортування без тари відповідно до Додатку II MARPOL 73/78 і Кодексом IBC

Не актуально.

Розділ 15: Нормативна інформація

15.1 Правові акти в сфері безпеки, захисту здоров'я і навколишнього середовища/особливі правові акти, застосовні до речовини або суміші

Клас небезпеки SARA Гостра

Реєстр						
Компонент	**CAS**	**Канада, DSL**	**Канада, NDSL**	**EC EINECS**	**EC ELNICS**	**TSCA**
Гуанідинтіоціанат	593-84-0	Так	Ні	Так	Ні	Так

Канада

Охорона праці

Канада - Інформаційна система щодо небезпечних матеріалів на робочих місцях (WHMIS) - Класифікація речовин

•Гуанідинтіоціанат 593-84-0 В списку не вказано

Канада - WHMIS - Перелік інгредієнтів, інформація про які підлягає розкриттю

•Гуанідинтіоціанат 593-84-0 В списку не вказано

Навколишнє середовище

Канада - Закон Канади про охорону навколишнього середовища (CEPA) - Список пріоритетних речовин

•Гуанідинтіоціанат 593-84-0 В списку не вказано

Сполучені Штати Америки

Охорона праці

США - Управління охорони праці (OSHA) - Забезпечення безпеки виробничого процесу - Високонебезпечні хімічні речовини

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - OSHA - Хімічні речовини, що підлягають особливому контролю

•Гуанідинтіоціанат 593-84-0 В списку не вказано

Навколишнє середовище

США - Закон про чисте повітря (CAA), 1990 - Небезпечні речовини, що забруднюють повітря

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - Акт про комплексне реагування, компенсації і відповідальності за шкоду навколишньому середовищу (CERCLA)/Закон про поліпшення фінансування та перерозподіл повноважень (SARA) - Небезпечні речовини та їх підзвітні кількості

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - CERCLA/SARA - Радіонукліди та їх підзвітні кількості

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - CERCLA/SARA - Розділ 302 Надзвичайно небезпечні речовини. Закон про планування дій при надзвичайних ситуаціях і право суспільства на інформацію (EPCRA) - підзвітні кількості

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - CERCLA/SARA - Розділ 302 Надзвичайно небезпечні речовини. Порогові заплановані кількості (TPQ)

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - CERCLA/SARA - Розділ 313 - Сповіщення про викиди

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - CERCLA/SARA - Розділ 313 - Список стійких біоакумулятивних токсичних речовин

•Гуанідинтіоціанат 593-84-0 В списку не вказано

США - Каліфорнія

Навколишнє середовище

США - Каліфорнія - Пропозиція 65 - Список канцерогенів		
•Гуанідинтіоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Ембріофетальна токсичність		
•Гуанідинтіоціанат	593-84-0	*В списку не вказано*
США - Каліфорнія - Пропозиція 65 - Максимальні допустимі рівні дози (MADL)		
•Гуанідинтіоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Не несе значимого ризику (NSRL)		
•Гуанідинтіоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Репродуктивна токсичність - Вплив на жіночий організм		
•Гуанідинтіоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Репродуктивна токсичність - Вплив на чоловічий організм		
•Гуанідинтіоціанат	593-84-0	В списку не вказано

15.2 Оцінка хімічної безпеки

Оцінка хімічної безпеки не проводилась.

Розділ 16: Додаткова інформація

Відповідні фрази (код і весь текст)

H302 – Шкідливо в разі ковтання
H313 – Може завдати шкоди у разі контакту зі шкірою
H320 – Викликає подразнення очей

Відмова від відповідальності/ обмеження відповідальності

Представлені вище відомості базуються на доступних нам даних з упевненістю в їх точності. В зв'язку з тим, що представлена інформація може бути використана в незалежних від нас та невідомих нам умовах, ми не несемо відповідальності за наслідки її використання, і всі особи, які отримують цю інформацію, повинні самостійно приймати рішення щодо наслідків застосування, властивостей, засобів захисту та способів утилізації відповідно до конкретних умов застосування. Ми не поручаємо, не даємо жодних гарантій та зобов'язань, явних або передбачуваних (включаючи гарантії придатності або товарної придатності для конкретної цілі), щодо матеріалів та точності даної інформації, отриманих при їх використанні результатів, а також небезпек, пов'язаних із використанням даного матеріалу. При поводженні з матеріалом та його використанні слід проявляти обережність. Представлена вище інформація передана добросовісно та з упевненістю в її точності. Ми надаємо всю інформацію, що стосується передбачуваного використання матеріалу, станом на момент публікації. Однак, у разі небажаних наслідків, пов'язаних із даним продуктом, цей паспорт з безпеки продукту не є і не може бути заміною консультації з відповідним спеціалістом.

Скорочення
NDA = Дані відсутні

安全数据表
生效日期：2021 年 1 月
更换日期：2020 年 9 月

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

第 1 章：物质/混合物标识和公司/企业标识

1.1 产品标识符

产品名称 **Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**

产品代码 900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 物质或混合物的有关确定用途及其使用建议

有关确定用途 实验室使用

1.3 供应商安全数据表详情

制造商 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US: techsupport@cepheid.com

电话（通用） 1 (888) 838-3222 - 美国（选 2）

电话（通用） 1 (408) 541-4191 - 美国境外

供应商 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
瑞典
www.cepheidinternational.com
EU: support@cepheideurope.com

电话（通用） +33 563 825 319

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
Australia
www.cepheidinternational.com
ANZ: TechSupportANZ@cepheid.com

电话（澳大利亚） 1800 107 884

1.4 紧急电话号码

制造商 1 (800) 535-5053 - INFOTRAC - 24 小时紧急联系

制造商 1 (352) 323-3500 - 美国境外

第 2 章：危险标识

EU/EEC

根据: 第 1272/2008 号规章（欧共体）(CLP)/REACH 1907/2006 [修订版 453/2010]

2.1 物质或混合物的分类

CLP

以下安全数据表是针对最终制成混合品，仅如实验室中所使用。产品含有微珠和试剂，装于盒中或盒外的容器中。对于披露某些组件信息的豁免是根据 CLP 第 1(5)(d) 条和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
未分类

2.2 标签元素

CLP

危险声明 无需任何标签要素

2.3 其他危险

CLP

依据第 1272/2008 号 (EC) 法规 (CLP)，此材料不属于有危害材料。

UN GHS（使用于产品上的标签内容）

根据: 联合国 (UN) 全球危险化学品统一分类和标签制度 (GHS)

2.1 物质或混合物的分类

GHS 危险报表（分类）

急性经口毒性 5
轻度皮肤刺激 3
眼轻度刺激 2B

2.2 标签元素

标签元素

警告

危险声明

吞入有害。
与皮肤接触可能有害。
导致眼睛刺激。

防范声明

预防 处理之后要彻底清洗双手。

响应 发生皮肤刺激时：获得医疗指导/就医治疗。
进入眼睛时：小心地用水冲洗若干分钟。佩戴隐形眼镜时，如果方便就将其取下，然后继续冲洗。
眼睛刺激持续时：获得医疗指导/就医治疗。
感到身体不适时，呼叫解毒中心或医生/医师。

2.3 其他危险

UN GHS 根据全球统一分类和标签制度（GHS），认为该产品是危险品

美国（US）
根据: OSHA 29 CFR 1910.1200 HCS

2.1 物质或混合物的分类

OSHA 的 HCS2012 眼轻度刺激 2B

2.2 标签元素

OSHA 的 HCS2012

危险说明 吞入有害。
与皮肤接触可能有害。
导致眼睛刺激。

警示性说明

预防 处理之后要彻底清洗双手。

响应 进入眼睛时：小心地用水冲洗若干分钟。佩戴隐形眼镜时，如果方便就将其取下，然后继续冲洗。
眼睛刺激持续时：获得医疗指导/就医治疗。

2.3 其他危险

OSHA 的 HCS2012 根据美国法规（29 CFR 1910.1200 - 危害通识标准），认为该产品属于非危险品。

加拿大
根据: 加拿大 - 工作场所危险物质信息系统

2.1 物质或混合物的分类

WHMIS 未分类

2.2 标签元素

WHMIS 不要求标签元素。

2.3 其他危险

WHMIS 在加拿大，根据工作场所有害物质信息系统（WHMIS），认为上述产品不是危险品。

2.4 其他信息

所有其他制剂、颗粒和其他组分的浓度在混合物中均低于 1%，或者根据美国危害通识法规 (29 CFR 1910.1200)、欧盟物质或混合物分类与标签指令或全球物质或混合物分类与标签统一制度均不被认为是危险物质。

第 3 章：成分构成/信息

3.1 物质

该材料不符合某种物质的标准。

3.2 混合物

构成					
化学名称	**标识符**	**%**	**LD50/LC50**	**按规章/指令分类**	**注解**
硫氰酸胍	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**EU CLP**：急性毒性 5、H302、H313、H320 **UN GHS**：急性毒性 5（口服）；皮肤刺激。3；眼刺激 2B **OSHA HCS 2012:** 急性毒性 5（口服）；眼刺激 2B	无可用数据

第 4 章-急救措施

4.1 急救措施描述

吸入

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。将受害者移至新鲜空气处。如果呼吸困难，就施用氧气 如果受害人吸入该物质，就不要使用口对口方法；借助配备单向阀或其他适当的呼吸医疗设备的袖珍面罩来给予人工呼吸 如果受害者没有呼吸，就给予人工呼吸。

皮肤

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。对于轻微的皮肤接触，避免在未受影响的皮肤上蔓延物质 在与物质接触的情况下，立即用大量的水冲洗皮肤至少 20 分钟 移走并隔离被沾染的衣服。

眼睛

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。在与物质接触的情况下，立即用大量的水冲洗眼睛至少 20 分钟。眼睛刺激持续时：获得医疗指导/就医治疗。

摄入

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。如果吞入，用水漱口（只有当伤员意识清楚时）。不要催吐 如果受害人摄入该物质，就不要使用口对口方法 如果摄入应立即就医。

4.2 急性及缓发的最重要症状及效应

请参阅第 11 章 - 毒物学信息

4.3 任何需要立即就医及特别治疗的症候

对医生的注释

所有治疗措施均应根据所观察到的患者的痛苦症状和体征进行。应考虑可能发生过度暴露于非本品材料的可能性。

第 5 章-消防措施

5.1 灭火介质

适用的灭火介质

大火：化学干粉、二氧化碳、抗溶性泡沫或喷水
小火：化学干粉，二氧化碳或喷水

不适用的灭火介质

无可用数据

5.2 由物质或混合物产生的特殊危险

异常火灾和爆炸危险

盛装试剂的塑料检测盒可能会散发碳氧化物、硫氧化物、氮氧化物有毒蒸气。

有害燃烧产物

无可用数据

5.3 供消防队员采纳的建议

建筑消防员的防护服在火情中只能提供有限的保护；它在可能与物质直接接触的溢出情况下无效穿上制造商专门推荐的化学防护服。
製造業者が推奨する化学品防護服を着用する。熱に対する保護は、ある程度、またはまったく提供されない。
它可能提供很少或根本没有提供热保护配戴正压自给式呼吸装置（SCBA）。
小火：如果能够无风险地完成，就从火区移出容器。

第 6 章-意外释放防范措施

6.1 个人预防措施、防护装备和紧急程序

个人预防措施	一旦盒子断裂，则适用于这些个人预防措施。穿戴适当的防护服。切勿踩踏泄漏物。除非穿着适当的防护服，否则不要触摸损坏的容器或溢出的材料。对封闭区域进行通风。
应急程序	如果在一般条件下并且按照推荐的方法使用材料，预计不必要执行应急程序

6.2 环保预防措施

防止进入水道、下水道、地下室或封闭区域。

6.3 用于遏制/净化的方法和材料

遏制/净化措施	对于少量撒漏，戴手套并用纸巾吸附撒漏物。切勿将撒漏的材料冲刷到排水管道中予以处置。

6.4 其他各章的参考

请参阅第 8 章 - 接触控制/个人防护以及第 13 章 - 处置注意事项

第 7 章-搬运和贮存

7.1 用于安全处理的预防措施

搬运	无需任何特殊操作。如果盒子断裂，避免接触撒漏的试剂。 避免与皮肤和眼睛接触。

7.2 包括任何不相容性的安全贮存条件

贮存	按产品标签予以储存。远离不相容材料上锁贮存。将容器/包装在阴凉、通风良好之处保持密闭

7.3 特定最终用途

请参阅第 1.2 条 - 有关确定用途

第 8 章-接触控制/个人防护

8.1 控制参数

	接触限值/指南			
	硫氰酸胍	**ACGIH**	**NIOSH**	**OSHA**
硫氰酸胍	TWA	未确立	未确立	未确立

8.2 接触控制

工程措施/控制
应当使用良好的通用通风设施。通风速率应当与环境相配。如果适用，使用工艺外罩、局部排气通风或其它工程控制设施，以保持空气中的浓度低于推荐的接触限值。如果尚未确定接触限值，就将空气中的浓度保持在可接受的水平。

个人防护装备

呼吸
如果在一般条件下按照推荐方法使用材料，无需使用呼吸防护装置。否则，遵循 29 CFR 1910.134 或欧洲标准 EN 149 中的 OSHA 呼吸防护装置规定。如果超过接触限值或出现症状，就使用 NIOSH/MSHA 或欧洲标准 EN 149 认可的呼吸器。

眼睛/面部
佩戴防化学剂飞溅护目镜。

皮肤/身体
穿戴防护服

环境接触控制
遵守厂区管理和废物处置最佳规范。

略语表
OSHA =职业安全和健康管理局
TWA =时间加权平均值根据 8 小时/天、40 小时/周的接触量来确定

第 9 章-物理性质和化学性质

9.1 有关物理性质和化学性质的信息

材料描述			
外形	液体	颜色	无色
气味	无味	气味阈值	数据缺乏
一般性质			
沸点	100 ° C (212 ° F)	熔点/凝固点	0 ° C (32 ° F)
分解温度	数据缺乏	pH 值	3.3 至 8.8
比重/相对密度	= 1 水=1	水溶解度	可溶 100%
粘度	数据缺乏	易爆性质：	数据缺乏
氧化性性质：	数据缺乏		
挥发性			
蒸气压力	极小	蒸气密度	数据缺乏
蒸发速率	极小		
易燃性			
闪点	数据缺乏	爆炸上限	数据缺乏
爆炸下限	数据缺乏	自燃点	数据缺乏
易燃性（固体、气体）：	数据缺乏		
环境方面			
辛醇/水分配系数	数据缺乏		

9.2 其他信息

未注明额外的物理和化学参数

第 10 章：稳定性和反应性

10.1 反应性

在正常使用条件下，未知有危险反应。

10.2 化学稳定性

稳定。

10.3 危险反应的可能性

不会发生危险的聚合反应。

10.4 应避免的情况

不相容的材料。燃烧盛装试剂的塑料检测盒可能会释放有毒副产物。

10.5 不相容的材料

酸。

10.6 危险的分解产物

燃烧盛装试剂的塑料检测盒可能会释放有毒副产物。

第 11 章-毒物学信息

11.1 有关毒物学效应的信息

组成成分		
硫氰酸胍	593-84-0	**急性毒性：**腹腔-小鼠 LD50 • 593 mg/kg

GHS 危险种类	危险类别
急性毒性	**EU/CLP•**数据缺乏 **UN GHS•**急性毒性 - 摄入/口服 - 5 类 **OSHA 的 HCS2012•**数据缺乏
皮肤腐蚀/刺激	**EU/CLP•**数据缺乏 **UN GHS•**皮肤有轻度刺激 3 类 **OSHA 的 HCS2012•**数据缺乏
严重眼损伤/刺激	**EU/CLP•**数据缺乏 **UN GHS•**眼睛有轻度刺激 2B 类 **OSHA 的 HCS2012•**轻度眼睛刺激 2B 类
皮肤过敏	**EU/CLP•**数据缺乏 **UN GHS•**数据缺乏 **OSHA 的 HCS2012•**数据缺乏
呼吸道过敏	**EU/CLP•**数据缺乏 **UN GHS•**数据缺乏 **OSHA 的 HCS2012•**数据缺乏

GHS 危险种类	危险类别
误吸危害	**EU/CLP**•数据缺乏 **UN GHS**•数据缺乏 **OSHA 的 HCS2012**•数据缺乏
致癌性	**EU/CLP**•数据缺乏 **UN GHS**•数据缺乏 **OSHA 的 HCS2012**•数据缺乏
生殖细胞致突变性	**EU/CLP**•数据缺乏 **UN GHS**•数据缺乏 **OSHA 的 HCS2012**•数据缺乏
针对生殖的毒性	**EU/CLP**•数据缺乏 **UN GHS**•数据缺乏 **OSHA 的 HCS2012**•数据缺乏

潜在健康影响

吸入
急性（立即） 可能引起刺激
慢性（缓发） 无可用数据
皮肤
急性（立即） 导致轻微的皮肤刺激
慢性（缓发） 无可用数据
眼睛
急性（立即） 造成眼刺激
慢性（缓发） 无可用数据
摄入
急性（立即） 如果吞入可能是有害的
慢性（缓发） 无可用数据

略语表
LD =致死剂量

第 12 章-生态学信息

12.1 毒性
LC50（孔雀鱼）：89.1 mg/L @ 96 小时

12.2 持久性和降解性
材料数据缺失。

12.3 生物累积的潜力
材料数据缺失。

12.4 土壤中的移动性
材料数据缺失。

12.5 PBT 及 vPvB 评估的结果
尚未进行 PBT 和 vPvB 评估。

12.6 其他不良效应

未发现研究成果。

第 13 章-处置注意事项

13.1 废物处理方法

产品废物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。
包装废弃物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。

13.2 其他信息

生物样本、转移设备以及用过的检测盒应被视为能够传播传染性病原体，必须采取标准预防措施。有关如何正确丢弃用过的检测盒和未使用过的试剂的信息，请遵循您所在机构的环境废物管理程序。这些材料可能会显示出需要为其执行特定的国家或地区的处置程序的化学危险废物的特性。如果国家或地区的法规没有明确的妥善处置规定，生物样本和使用过的检测盒应根据 WHO（世界卫生组织）的医疗废弃物处理和处置原则来处理。

第 14 章-运输信息

	14.1 UN 编号	14.2 UN 正式运输名称	14.3 运输危险分类	14.4 包装组	14.5 环境危害
DOT	未规定	未规定	未规定	未规定	不适用
TDG	未规定	未规定	未规定	未规定	不适用
IMO/IMDG	未规定	未规定	未规定	未规定	不适用
IATA/ICAO	未规定	未规定	未规定	未规定	不适用

14.6 用户特殊防护措施

未列明。

14.7 根据 MARPOL 73/78 的附件 II 以及 IBC 规范规定的散装运输

不相关。

第 15 章-法规信息

15.1 针对特定物质或混合物的安全、卫生和环境条例/法规

SARA 危险性分类 急性

名录						
成分	CAS	加拿大 DSL	加拿大 NDSL	欧盟 EINECS	欧盟 ELNICS	TSAC
硫氰酸胍	593-84-0	是	否	是	否	是

加拿大

劳动

加拿大 - 加拿大工作场所危险物质信息系统 (WHMIS) - 物质分类

•硫氰酸胍	593-84-0	未列出

加拿大 - 加拿大工作场所危险物质信息系统 (WHMIS) - 组分披露列表

•硫氰酸胍	593-84-0	未列出

环境

加拿大 - 环境保护法 (CEPA) - 优先重点物质列表

•硫氰酸胍	593-84-0	未列出

美国

劳动

美国 - 职业安全与健康管理局 (OSHA) - 制程安全管理 - 高度危险化学品

•硫氰酸胍	593-84-0	未列出

美国 - 职业安全与健康管理局 (OSHA) - 专门监管化学品

•硫氰酸胍	593-84-0	未列出

环境

美国 - CAA（清洁空气法）- 1990 年危险空气污染物

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 危险物质及其可报告数量

•硫氰酸胍	593-84-0	未列出

国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 放射性核素及其可报告数量

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质 EPCRA RQ

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质 TPQ

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - 排放报告

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - PBT 化学品列表

•硫氰酸胍	593-84-0	未列出

美国 – 加利福尼亚

环境

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 致癌物清单		
•硫氰酸胍	593-84-0	未列出
美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 发育毒性		
•硫氰酸胍	593-84-0	未列出
美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 最大容许剂量水平 (MADL)		
•硫氰酸胍	593-84-0	未列出
美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 无显著风险级别 (NSRL)		
•硫氰酸胍	593-84-0	未列出
美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 女性		
•硫氰酸胍	593-84-0	未列出
美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 男性		
•硫氰酸胍	593-84-0	未列出

15.2 化学安全评估

未进行化学安全评估。

第 16 章-其他信息

相关习语（规范及全文）

H302 – 吞入有害。
H313 – 与皮肤接触可能有害。
H320 – 导致眼睛刺激。

免责声明/责任声明

以上信息基于对于我们的可用数据，而且相信是正确的。由于对信息的应用可能会在超出我们控制的条件下和以我们所不熟悉的条件进行，因此我们对其使用的任何结果概不承担任何责任，而且收到此信息的所有人士均务必自行确定其特定应用条件下的效能、性能、防护和处置方法。未就信息所涵盖的材料、其准确性、因使用材料而获得的结果或与使用材料相关的危害作出任何明示或暗示的表示、担保或保证（包括对特定目的下适用性或适销性的担保）。操作或使用本材料应小心谨慎。以上信息以诚信提供，而且相信是准确的。截至签发日期，我们提供有关可预见材料操作的所有信息。然而，一旦发生与本品相关的恶性事故，本安全数据表却不是，而且也不旨在是向接受过适当训练人员咨询的替代。

略语表
NDA = 无可用数据

安全データシート
発効日：2021 年 1 月
優先日付：2020 年 9 月

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

セクション 1: 物質・混合物、および企業・事業の識別

1.1 製品識別子

製品名 **Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert XpressSARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV**

製品コード 900-0731; GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; XPRSFLU/RSV-CE-120; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; OMNISARS-COV2-10; XPRSARS-COV2-DOD

1.2 物質や混合物の特定された関連用途、および推奨されない用途

特定された関連用途 研究用

1.3 安全データを提供した供給業者の詳細

製造業者 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US: techsupport@cepheid.com
電話（一般） 1 (888) 838-3222 -米国オプション 2
電話（一般） 1 (408) 541-4191 -米国外

販売業者 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
EU: support@cepheideurope.com
電話（一般） +33 563 825 319

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
Australia
www.cepheidinternational.com
ANZ: TechSupportANZ@cepheid.com
電話番号 (オーストラリア) 1800 107 884

1.4 緊急電話番号

製造業者 1 (800) 535-5053 - INFOTRAC - 24 時間緊急用
製造業者 1 (352) 323-3500 -米国外

セクション 2: 危険性識別

EU/EEC
準拠: 指令（EC）1272/2008 (CLP)/REACH 1907/2006 [453/2010 による改訂]

2.1 物質や混合物の分類

CLP

以下の SDS は、研究所で使用されるため、最終完全混合物製品用のみです。本製品は、カートリッジまたは装置外の容器内にビーズおよび試薬を含んでいます。一部の成分の情報の開示の免除は、CLP 項目 1(5)(d)および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
未分類

2.2 ラベル要素

CLP

危険有害性情報 ラベル要素は必要ありません。

2.3 その他危険性

CLP

規定(EC) No. 1272/2008 (CLP) に準じて、本剤は危険物とみなされません。

UN GHS (製品に使用されている表示の内容)
準拠: UN 化学品の分類および表示に関する世界調和システム

2.1 物質や混合物の分類

GHS 危険有害性情報（分類）

急性毒性　経口５
軽度の皮膚刺激 3
軽度の眼刺激2B

2.2 ラベル要素

UN GHS

警告

危険有害性情報

飲み込むと有害。
皮膚に付着すると有害な可能性。
眼への刺激を引き起こす。

予防情報

予防 使用後は: をしっかりと洗ってください。

反応 皮膚に刺激が生じた場合：医師の助言／手当てを受ける。
目に入った場合：数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目への刺激が続く場合：医師の助言／手当てを受ける。
気分が悪い場合、毒物センターあるいは医師に連絡する。

2.3 その他危険性

UN GHS 危険化学品分類表示の世界調和システム（GHS）では、本製品は危険な物質と考慮されています。

米国（US）

準拠: OSHA 29 CFR 1910.1200 HCS

2.1 物質や混合物の分類

OSHA HCS 2012 軽度の眼刺激2B

2.2 ラベル要素

OSHA HCS 2012

危険有害性情報 飲み込むと有害。
皮膚に付着すると有害な可能性。
眼への刺激を引き起こす。

注意書き

予防 使用後は 手をしっかりと洗ってください。

応答 目に入った場合：数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目への刺激が続く場合：医師の助言／手当てを受ける。

2.3 その他危険性

OSHA HCS 2012 米国規定(29 CFR 1910.1200 - 危険有害性周知基準)に基づき、本製品は危険物とみなされません。

カナダ

準拠: WHMIS

2.1 物質や混合物の分類

WHMIS 未分類

2.2 ラベル要素

WHMIS ラベル要素は必要ありません。

2.3 その他危険性

WHMIS カナダでは、上述の製品は作業場にある危険物に関する情報システム (WHMIS)に基づき危険物とみなされません。

2.4 その他情報

その他のすべての試薬、ビーズ、その他の成分は、混合物の 1%未満または米国ハザード通信規制（29 CFR 1910.1200）、物質または混合物の分類と表示に関する EU 指令、または化学品の。

セクション 3: 成分の組成・情報

3.1 物質

本剤は、材料区分を満たしません。

3.2 混合物

合成物					
化学名	**識別子**	**%**	**LD50/LC50**	**規定/指針に基づく分類**	**コメント**
チオシアン酸グアニジン	**CAS:** 593-84-0 **EINECS:** 209-812-1	10〜20%	593 mg/kg	**EU CLP**：急性毒性 5、H302、H313、H320 **UN GHS**：急性毒性 5（経口）、皮膚のかゆみ 3、目のかゆみ 2B **OSHA HCS 2012**：急性毒性 5（経口）、目のかゆみ 2B	NDA

セクション 4: 応急処置手段

4.1 応急措置手段

吸引
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。被災者を外気に当てる 呼吸困難の場合は、酸素を吸入させる 被災者が物質を吸引した場合、口移し式人工呼吸を行ってはならない; 一方向バルブの付いたポケットマスクや、その他の適切な呼吸医療装置を使って人工呼吸を行う。被災者が呼吸していない場合は、人工呼吸を施す。

皮膚
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。皮膚に少し接触した場合は、接触していない部分に物質が広がらないようにする 物質に触れた場合、最低 20 分間、流水で直ちに皮膚を洗浄する 汚染された服を脱ぎ、隔離してください。

目
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。物質と接触した場合は、最低 20 分間、直ちに流水で目を洗浄する。目への刺激が続く場合：医師の助言／手当てを受ける。

摂取
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。飲み込んだ場合は、水で口をゆすいでください（意識がある場合）。嘔吐を誘発しないでください。被災者が物質を摂取した場合、口移し式人工呼吸を行ってはならない 本剤を飲み込んだ場合は、直ちに病院に行って下さい。

4.2 もっとも重要な症状と影響、急性および遅発性

第十一項　毒性に関する情報を参照してください。

4.3 直ちに医学的配慮と特別治療を必要とする兆候

医師へのメモ
治療はすべて、患者の苦痛の兆候および症状に基づき行われる必要があります。本製品以外の物質に著しくさらされた可能性について考慮する必要があります。

セクション 5: 消火手段

5.1 消火剤

適切な消火剤	大規模火災: 乾燥した化学品、二酸化炭素、水溶性液体用泡消火剤、散水 小規模火災: 乾燥した化学品、二酸化炭素、散水
不適切な消火剤	データなし

5.2 物質や混合物から発生する特別な危険

異常な火災と爆発の危険	試薬を含むプラスチック製カートリッジは、炭素酸化物、硫黄酸化物、窒素酸化物の有毒な蒸気を放出することがあります。
有害な燃焼生物	データなし

5.3 消防士への助言

建物火災用消防用服が火災状況で提供する保護は限定されている。流出した状況では物質に直接接触する可能性があ るため、効果がない製造業者が推奨する化学品防護服を着用する。
熱に対する保護は、ある程度、またはまったく提供されないことがある陽圧自給式呼吸器（SCBA）を着用する。
小規模火災: 危険を冒さずにできる場合は、火災区域 から容器を移動させる動かす。

セクション 6: 漏出時の措置

6.1 人体に対する注意事項

人体に対する注意事項	カートリッジが破損した場合、これらの人体に対する予防措置が適用されます。適切な保護服を着用してください。本剤がこぼれている場所を歩かないでください。適切な保護具を着用しない場合は、損傷した容器や流出物質に触れてはならない 囲まれた区域を換気する。
応急措置	本剤が通常の状況で推奨された方法で使用される場合は、特別に必要とされる緊急措置はありません。

6.2 影響に対する注意事項

水路、下水道、地下室、囲まれた区域に流入するのを防ぐ。

6.3 閉じ込めと清掃の手段と物質

閉じ込め・清掃の手段	少量の流出の場合は、手袋を着用し、ペーパータオルで流出を吸収してください。流出した物質を排水溝に廃棄しないでください。

6.4 他のセクションへの言及

第八項　爆発管理/安全保護、および第十三項　廃棄時の注意事項を参照してください。

セクション 7: 取り扱いと保管

7.1 安全な取り扱いについての注意

取り扱い 特別な取扱いは必要ありません。カートリッジが破損した場合、漏出した試薬に触れないようにしてください。皮膚に付着したり、目に入らないようにしてください。

7.2 安全な保管の条件、不適合性を含む

保管 製品ラベルに従って保管してください。互換性を持たない物質から話してください。鍵をかけて保管する。容器/パッケージをしっかりと密閉し、涼しく、風通しの良い場所に保管してください。

7.3 具体的な最終用途

第十二項　関連する使用方法に関する情報を参照してください。

セクション 8: 暴露管理・個人保護

8.1 管理パラメータ

	曝露限度／ガイドライン			
	結果	**ACGIH**	**NIOSH**	**OSHA**
チオシアン酸グアニジン	TWA	設定なし	設定なし	設定なし

8.2 曝露管理

工学的手段・管理 十分な通気を確保してください。通規率は状況に応じて適切に調整してください。該当する場合は、包囲装置、局所排気装置、またはその他のエンジニアリング。コントロール装置を使って、空気中の粉塵レベルが推奨暴露限界を超えないようにしてください。暴露レベルが確定されていない場合は、許容範囲の粉塵量を維持してください。

個人用保護具

呼吸器官 物質が通常の状況でかつ推奨通りに使用される場合、呼吸装置が必要になるとは予想されません。もし必要な場合、OSHA 呼吸器規制に関しては、29 CFR 1910.134 または 欧州標準 EN 149 をご覧ください。暴露基準を超える場合、あるいは症状が発症した場合は、NIOSH/MSHA または 欧州標準 EN 149 保護マスクをご使用ください。

目・顔面 化学物飛散防止ゴーグルを着用してください。

皮膚・人体 保護服を着用してください。

環境暴露管理 現場管理および廃棄物の取り扱いは十分注意して行ってください。

略語について
OSHA =労働安全衛生局
TWA =時間加重平均値は、8 時間/1 日、40 時間/1 週間の暴露に基づいた数値です。

セクション 9: 物理的および化学的特性

9.1 物理的および化学的特性

材料の説明			
物理的形状	液体	色	透明で無色
臭気	無臭	臭気限界	データ不足
一般的性質			
沸騰点	100 °C (212 °F)	融解点・凝固点	0 °C (32 °F)
分解温度	データ不足	pH	3.3 至 8.8
比重・相対密度	= 1 Water=1	水溶性	可溶性 100%
粘性	データ不足	爆発特性	データ不足
酸化特性	データ不足		
揮発度			
蒸気圧	最小	蒸気密度	データ不足
蒸発速度	最小		
可燃性			
引火点	データ不足	UEL	データ不足
LEL	データ不足	自己発火	データ不足
可燃性（固体、ガス）	データ不足		
環境曝露管理			
オクタノール・水分配係数	データ不足		

9.2 その他情報

その他に物理的および化学的パラメータの記載はありません。

セクション 10: 安定性と反応性

10.1 反応性

通常の使用において、危険反応は報告されていません。

10.2 化学安定性

安定

10.3 有害反応の可能性

危険物のポリメリゼーションは発生しません。

10.4 回避すべき条件

規定物質。試薬を含むプラスチック製カートリッジを燃焼すると、毒性の副産物を放出する可能性があります。

10.5 不適合物質

酸。

10.6 有害分解性生物

試薬を含むプラスチック製カートリッジを燃焼すると、毒性の副産物を放出する可能性があります。

セクション 11: 毒性情報

11.1 毒性効果

成分		
チオシアン酸グアニジン	593-84-0	**急性毒性**:腹腔内-マウス LD50 • 593 mg/kg

GHS 特性	分類
急性毒性	**EU/CLP**•データ不足 **UN GHS**•急性毒性 - 摂取／経口 - 分類 5 **OSHA HCS 2012**•データ不足
皮膚の腐食・炎症	**EU/CLP**•データ不足 **UN GHS**•皮膚の軽度の刺激分類 3 **OSHA HCS 2012**•データ不足
重度の目の損傷・炎症	**EU/CLP**•データ不足 **UN GHS**•目軽度の刺激分類 2B **OSHA HCS 2012**•軽度の目の炎症分類 2B
皮膚感作性	**EU/CLP**•データ不足 **UN GHS**•データ不足 **OSHA HCS 2012**•データ不足
呼吸器感作性	**EU/CLP**•データ不足 **UN GHS**•データ不足 **OSHA HCS 2012**•データ不足
発癌性	**EU/CLP**•データ不足 **UN GHS**•データ不足 **OSHA HCS 2012**•データ不足
生殖細胞変異原性	**EU/CLP**•データ不足 **UN GHS**•データ不足 **OSHA HCS 2012**•データ不足
生殖毒性	**EU/CLP**•データ不足 **UN GHS**•データ不足 **OSHA HCS 2012**•データ不足
STOT-SE	**EU/CLP •データ不足** **UN GHS•データ不足** **OSHA HCS 2012•データ不足**

考えられる健康への影響

吸引
急性（即座） 過敏症が生じる場合があります。
慢性（遅発性） データなし
皮膚
急性（即座） 皮膚に軽度の刺激を起こす可能性があります。
慢性（遅発性） データなし
目
急性（即座） 目の炎症を起こす。
慢性（遅発性） データなし

摂取
急性（即座） 飲み込んだ場合、健康に支障を生じる可能性があります。
慢性（遅発性） データなし

略語について
LD =致死量

セクション 12: 生態学的情報

12.1 毒性
LC50（グッピー）：96 時間で 89.1 mg/L

12.2 持続性と分解性
実態データが不足しています。

12.3 生体内蓄積能
実態データが不足しています。

12.4 土壌中移動性
実態データが不足しています。

12.5 PBT と vPvB 評価の結果
PBT および vPvB アセスメントは行われていません。

12.6 その他有害影響
そのような研究結果はありません。

セクション 13: 廃棄上の注意

13.1 廃棄物処理手段
製品廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。
包装廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

13.2 その他情報
生物検体、移動器具および使用済みカートリッジは、標準的予防策を必要とする感染体(病原菌)を伝播する可能性があると見なしてください。使用済みカードリッジや、未使用の試薬の適切な廃棄については、当該施設の環境廃棄物手順に従ってください。これらは、国や地域の特別な廃棄手順に従う必要のある化学品有害廃棄物の特徴を示す可能性があります。国の法律や地域の条例により、適切な廃棄処理について、明確な指示が出されていない場合、生物検体や使用済みカートリッジは WHO（世界保健機関）の医療廃棄物の取り扱いおよび廃棄についてのガイドラインに従って廃棄してください。

Cepheid

安全データシート
発効日：2021 年 1 月
優先日付：2020 年 9 月

Xpert Flu/RSV XC; Xpert Xpress Flu; Xpert Flu+RSV Xpress
Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress SARS-COV-2
Xpert Xpress SARS-CoV-2/Flu/RSV

セクション 14: 輸送情報

	14.1 UN 番号	14.2 UN 正式輸送品目名	14.3 輸送有害性等級	14.4 包装等級	14.5 環境有害性
DOT	規制なし	規制なし	規制なし	規制なし	該当なし
TDG	規制なし	規制なし	規制なし	規制なし	該当なし
IMO/IMDG	規制なし	規制なし	規制なし	規制なし	該当なし
IATA/ICAO	規制なし	規制なし	規制なし	規制なし	該当なし

14.6 ユーザーに対する特別予防装置

指定なし。

14.7 MARPOL 73/78 の付属書と IBC コードに則ったバルク輸送

関連性なし。

セクション 15: 規制情報

15.1 物質や混合物についての具体的な安全、健康、環境規制・法律

SARA 危険分類 急性

在庫						
Component	CAS	カナダ DSL	カナダ NDSL	EU EINECS	EU ELNICS	TSCA
チオシアン酸グアニジン	593-84-0	あり	なし	あり	なし	あり

カナダ

作業

カナダ - WHMIS - 物質の分類
- チオシアン酸グアニジン 593-84-0 掲載外

カナダ - WHMIS -成分開示リスト
- チオシアン酸グアニジン 593-84-0 掲載外

環境

カナダ - CEPA- 優先物質リスト
- チオシアン酸グアニジン 593-84-0 掲載外

米国

作業

米国 OSHA - プロセス安全管理 - 非常に危険有害な化学品
- チオシアン酸グアニジン 593-84-0 掲載外

米国 OSHA - 特異制御化学物質
- チオシアン酸グアニジン 593-84-0 掲載外

環境

米国- CAA (大気汚染防止法) - 1990 有害大気汚染物質

•チオシアン酸グアニジン	593-84-0	掲載外

米国- CERCLA/SARA - 有害危険物質および法定基準量

•チオシアン酸グアニジン	593-84-0	掲載外

米国- CERCLA/SARA - 放射性核種および法定基準量

•チオシアン酸グアニジン	593-84-0	掲載外

米国- CERCLA/SARA 第 302 項　極めて有害な物質 EPCRA の報告義務量

•チオシアン酸グアニジン	593-84-0	掲載外

米国- CERCLA/SARA 第 302 項　極めて有害な物質 TPQ

•チオシアン酸グアニジン	593-84-0	掲載外

米国- CERCLA/SARA 第 313 項　排気量レポート

•チオシアン酸グアニジン	593-84-0	掲載外

米国- CERCLA/SARA 第 313 項　排出報告

•チオシアン酸グアニジン	593-84-0	掲載外

米国 - カリフォルニア

環境

米国カリフォルニア州住民投票事項 65-発がん性物質リスト

•チオシアン酸グアニジン	593-84-0	掲載外

米国カリフォルニア州住民投票事項 65-発達毒性

•チオシアン酸グアニジン	593-84-0	掲載外

米国カリフォルニア州住民投票事項 65-最大許容レベル

•チオシアン酸グアニジン	593-84-0	掲載外

米国カリフォルニア州住民投票事項 65-無リスク（安全）摂取量(NSRL)

•チオシアン酸グアニジン	593-84-0	掲載外

米国カリフォルニア州住民投票事項 65-生殖毒性-女性

•チオシアン酸グアニジン	593-84-0	掲載外

米国カリフォルニア州住民投票事項 65-生殖毒性-男性

•チオシアン酸グアニジン	593-84-0	掲載外

15.2 化学物質安全評価

化学的安全評価は実施されていません。

セクション 16: その他情報

関連表現（コードと全文）

H302 – 飲み込むと有害。
H313 – 皮膚に付着すると有害な可能性。
H320 – 眼への刺激を引き起こす。

免責条項・責任声明

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略語について
NDA = 該当データなし。

Safety Data Sheet
Effective Date: May, 2020
Supersedes Date: April, 2020

Xpert CT Assay
Xpert CT/NG Assay

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifier

Product Name **Xpert CT Assay; Xpert CT/NG Assay**
Product Code GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Relevant Identified Use(s) Laboratory use

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US: techsupport@cepheid.com
Telephone (General) 1 (888) 838-3222 - US Option 2
Telephone (General) 1 (408) 541-4191 - Outside of the US

Supplier Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
EU: support@cepheideurope.com
Telephone (General) 33 563 825 319 - EU

1.4 Emergency Telephone Number

Manufacturer 1 (800) 535-5053 - INFOTRAC - 24 hr Emergency
Manufacturer 1 (352) 323-3500 - Outside of the US

Section 2: Hazards Identification

EU/EEC

According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the Substance or Mixture

CLP The following SDS is for the final finished mixture product only as used in the laboratory. The product contains beads and reagents in the cartridge or in off-board containers. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

CLP

Hazard Statements
H302 – Harmful if swallowed
H313 – May be harmful in contact to skin
H320 – Causes eye irritation

Precautionary Statements

Prevention
P264 – Wash thoroughly after handling.
P270 – Do not eat, drink or smoke when using this product.

Response
P301+312 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.
P330 – Rinse mouth.

Storage/Disposal
P501 – Dispose of contents/or container in accordance with local, regional, national, and/or international regulations.

2.3 Other Hazards

CLP
According to Regulation (EC) No. 1272/2008 (CLP) this material is not considered hazardous.

UN GHS Revision 3 (Labeling Content Used on Products)

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

2.1 Classification of the Substance or Mixture

UN GHS
Acute Toxicity Oral 5
Skin Mild Irritation 5
Eye Mild Irritation 2B

2.2 Label Elements

UN GHS

WARNING

Hazard Statements
Harmful if swallowed
May be harmful in contact to skin
Causes eye irritation

Precautionary Statements

Prevention
Wash thoroughly after handling.

Response
If skin irritation occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Call a POISON CENTER or doctor/physician if you feel unwell.

Storage/Disposal
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

2.3 Other Hazards

UN GHS According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous.

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the Substance or Mixture

OSHA HCS 2012 Eye Mild Irritation 2B

2.2 Label Elements

OSHA HCS 2012

Hazard Statements	Causes eye irritation
Precautionary Statements	
Prevention	Wash thoroughly after handling.
Response	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage/Disposal	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

2.3 Other Hazards

OSHA HCS 2012 Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is not considered hazardous.

Canada
According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS Not classified

2.2 Label Elements

WHMIS No label element(s) required.

2.3 Other Hazards

WHMIS In Canada, the product mentioned above is not considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).

2.4 Other Information

All other reagents, beads, and other constituents are at concentrations less than 1% in the mixture or not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

Section 3: Composition/Information on Ingredients

3.1 Substances

Material does not meet the criteria of a substance.

3.2 Mixtures

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Guanidine Thiocyanate	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**EU CLP:** Acute Tox. 5, H302, H313, H320 **UN GHS:** Acute Tox. 5 (Orl); Skin Irrit. 5; Eye Irrit. 2B **OSHA HCS 2012:** Acute Tox. 5 (Orl); Eye Irrit. 2B	NDA

Section 4: First Aid Measures

4.1 Description of First Aid Measures

Inhalation First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move victim to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing.

Skin First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. For minor skin contact, avoid spreading material on unaffected skin. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Remove and isolate contaminated clothing.

Eye First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Obtain medical attention immediately if ingested.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Refer to Section 11 - Toxicological Information.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	LARGE FIRES: Dry chemical, CO_2, alcohol-resistant foam or water spray. SMALL FIRES: Dry chemical, CO_2 or water spray.
Unsuitable Extinguishing Media	No data available

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	Plastic cartridge containing reagents may emit toxic vapors of carbon oxides, sulfur oxides, nitrogen oxides.
Hazardous Combustion Products	No data available

5.3 Advice for Firefighters

Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.
Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.
Wear positive pressure self-contained breathing apparatus (SCBA).
SMALL FIRES: Move containers from fire area if you can do it without risk.

Section 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions	In the event a cartridge is broken these personal precautions are applicable. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate enclosed areas.
Emergency Procedures	No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

6.3 Methods and Material for Containment and Cleaning Up

Containment/ Clean-up Measures	For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.

6.4 Reference to Other Sections

Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7: Handling and Storage

7.1 Precautions for Safe handling

Handling No special handling necessary. If cartridge is broken avoid contact with spilled reagents.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Storage Store according to product labeling. Keep away from incompatible materials. Store locked up. Keep container/package tightly closed in a cool, well-ventilated place.

7.3 Specific End Use(s)

Refer to Section 1.2 - Relevant identified uses.

Section 8: Exposure Controls/Personal Protection

8.1 Control Parameters

	Exposure Limits/Guidelines			
	Result	**ACGIH**	**NIOSH**	**OSHA**
Guanidinium thiocyanate	TWA	Not established	Not established	Not established

8.2 Exposure Controls

Engineering Measures/Controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory Respiratory equipment is not expected to be necessary if material is used under ordinary conditions and as recommended. Otherwise, follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face Wear chemical splash safety goggles.

Skin/Body Wear protective clothing

Environmental Exposure Controls Follow best practice for site management and disposal of waste.

Key to abbreviations
OSHA = Occupational Safety and Health Administration
TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Reagents are clear, colorless liquids with no odor which are primarily buffered in aqueous solutions.
Color	Clear	Odor	Odorless
Odor Threshold	Data lacking		
General Properties			
Boiling Point	100 °C(212 °F)	Melting Point/Freezing Point	0 °C(32 °F)
Decomposition Temperature	Data lacking	pH	3.5 to 8.8
Specific Gravity/Relative Density	Data lacking	Water Solubility	Data lacking
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Data lacking	Vapor Density	Data lacking
Evaporation Rate	Data lacking		
Flammability			
	360 to 560 °F (182.2222 to 293.3333 °C) (Binding reagent)	UEL	Data lacking
LEL	Data lacking	Autoignition	Data lacking
Flammability (solid, gas)	Data lacking		
Environmental			
Octanol/Water Partition Coefficient	Data lacking		

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical Stability

Stable

10.3 Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4 Conditions to Avoid

Incompatible materials. Burning plastic cartridge containing reagents may liberate toxic byproducts.

10.5 Incompatible Materials

Acids, oxidizing agents.

10.6 Hazardous Decomposition Products

Burning plastic cartridge containing reagents may liberate toxic byproducts..

Section 11: Toxicological Information

11.1 Information on Toxicological Effects

Components		
Guanidinium thiocyanate	593-84-0	**Acute Toxicity:** Intraperitoneal-Mouse LD50 593 mg/kg

GHS Properties	Classification
Acute Toxicity	**EU/CLP**•Data lacking **UN GHS 3**•Acute Toxicity - Oral 5 - ATEmix (oral) = 2965 mg/kg **OSHA HCS 2012**•Data lacking
Skin Corrosion/Irritation	**EU/CLP**•Data lacking **UN GHS 3**•Skin Mild Irritation 3 **OSHA HCS 2012**•Data lacking
Serious Eye Damage/Irritation	**EU/CLP**•Data lacking **UN GHS 3**•Eye Mild Irritation 2B **OSHA HCS 2012**•Eye Mild Irritation 2B
Skin Sensitization	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Respiratory Sensitization	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Aspiration Hazard	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Carcinogenicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Germ Cell Mutagenicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Toxicity for Reproduction	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-SE	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-RE	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking

Potential Health Effects

Inhalation
Acute (Immediate) May cause irritation.
Chronic (Delayed) No data available

Skin
Acute (Immediate) Causes skin irritation.
Chronic (Delayed) No data available

Eye
Acute (Immediate) Causes eye irritation.
Chronic (Delayed) No data available

Ingestion
Acute (Immediate) Harmful if swallowed.
Chronic (Delayed) No data available

Key to abbreviations
LD = Lethal Dose

Section 12: Ecological Information

12.1 Toxicity

LC50 (guppy): 89.1 mg/l @ 96 h

12.2 Persistence and Degradability

Material data lacking.

12.3 Bioaccumulative Potential

Material data lacking.

12.4 Mobility in Soil

Material data lacking.

12.5 Results of PBT and vPvB Assessment

No PBT and vPvB assessment has been conducted.

12.6 Other Adverse Effects

No studies have been found.

Section 13: Disposal Considerations

13.1 Waste Treatment Methods

Product Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13.2 Other Information

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO (World Health Organization) medical waste handling and disposal guidelines.

Section 14: Transport Information

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Transport Hazard Class(es)	14.4 Packing Group	14.5 Environmental Hazards
DOT	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not applicable
TDG	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not applicable
IMO/IMDG	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not applicable
IATA/ICAO	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not applicable

14.6 Special Precautions for User

None specified.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Data lacking.

Section 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SARA Hazard Classifications Acute

Inventory						
Component	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidinium thiocyanate	593-84-0	Yes	No	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

•Guanidinium thiocyanate	593-84-0	Not Listed

Canada - WHMIS - Ingredient Disclosure List

•Guanidinium thiocyanate	593-84-0	Not Listed

Environment

Canada - CEPA - Priority Substances List

•Guanidinium thiocyanate	593-84-0	Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

•Guanidinium thiocyanate	593-84-0	Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

•Guanidinium thiocyanate	593-84-0	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

•Guanidinium thiocyanate	593-84-0	Not Listed

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16: Other Information

Relevant Phrases (code & full text)

H302 – Harmful if swallowed
H313 – May be harmful in contact to skin
H320 – Causes eye irritation

Disclaimer/ Statement of Liability

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections, and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

Key to abbreviations
NDA = No data available

Fiche de données de sécurité
Date d'entrée en vigueur : Mai 2020
Remplace la date : Avril 2020

Xpert CT Assay
Xpert CT/NG Assay

Section 1 : Identification de la substance/du mélange et de la compagnie/entreprise

1.1 Identifiant de produit

Nom du produit **Xpert CT Assay; Xpert CT/NG Assay**
Code produit GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Utilisations pertinentes identifiées de la substance ou du mélange et utilisations contre-indiquées

Utilisation(s) pertinente(s) identifiée(s) Utilisation en laboratoire

1.3 Coordonnées du fournisseur de la fiche de données de sécurité (FDS)

Fabricant Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
États-Unis
www.cepheid.com
États-Unis : techsupport@cepheid.com
Téléphone (général) 1 (888) 838-3222 - États-Unis Choix 2
Téléphone (général) 1 (408) 541-4191 - En dehors des États-Unis

Fournisseur Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Suède
www.cepheidinternational.com
UE : support@cepheideurope.com
Téléphone (général) 33 563 825 319 - UE

1.4 Numéro de téléphone d'urgence

Fabricant 1 (800) 535-5053 - INFOTRAC - Urgences 24 h/24
Fabricant 1 (352) 323-3500 - En dehors des États-Unis

Section 2 : Identification des risques

EU/EEC

Selon : Règlement (CE) N° 1272/2008 (CLP)/REACH 1907/2006 [modifié par le 453/2010]

2.1 Classification de la substance ou mélange

CLP La fiche de données de sécurité (FDS) suivante concerne uniquement le mélange fini final, tel qu'utilisé au laboratoire. Le produit contient des billes et des réactifs dans la cartouche ou dans des conteneurs externes. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

CLP

Mentions de danger	H302 – Nocif en cas d'ingestion H313 – Peut être nocif par contact cutané H320 – Provoque une irritation des yeux
Mises en garde	
Prévention	P264 – Se laver soigneusement après manipulation. P270 – Ne pas manger, boire ou fumer en manipulant ce produit.
Réponse	P301+P312 – EN CAS D'INGESTION : appeler immédiatement un CENTRE ANTIPOISON ou un médecin en cas de malaise. P330 – Rincer la bouche.
Stockage/Mise au rebut	P501 – Éliminer le contenu et/ou le récipient conformément aux réglementations locales, régionales, nationales et/ou internationales.

2.3 Autres dangers

CLP Selon le règlement (CE) n° 1272/2008 (CLP), ce produit n'est pas considéré dangereux.

SGH ONU Révision 3 (Contenu de l'étiquetage utilisé sur les produits)

Selon : Système général harmonisé (SGH) des Nations Unies concernant la classification et l'étiquetage des produits chimiques : Troisième édition révisée

2.1 Classification de la substance ou mélange

SGH ONU
Toxicité aiguë par voie orale 5
Légère irritation cutanée 5
Légère irritation oculaire 2B

2.2 Éléments de l'étiquette

SGH ONU

ATTENTION

Mentions de danger	Nocif en cas d'ingestion Peut être nocif par contact cutané Provoque une irritation des yeux
Mises en garde	
Prévention	Laver soigneusement après manipulation.
Réponse	En cas d'irritation cutanée : consulter un médecin. EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer. Si l'irritation oculaire persiste : consulter un médecin. Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.
Stockage/Mise au rebut	Éliminer le contenu et/ou le récipient conformément aux réglementations locales, régionales, nationales, et/ou internationales.

2.3 Autres dangers

SGH ONU Selon le Système général harmonisé de classification et d'étiquetage (SGH), ce produit est considéré dangereux.

États-Unis (É.-U.)
Selon : OSHA 29 CFR 1910.1200 HCS

2.1 Classification de la substance ou mélange

OSHA HCS 2012 Légère irritation oculaire 2B

2.2 Éléments de l'étiquette

OSHA HCS 2012

Mentions de danger Provoque une irritation des yeux

Mises en garde

Prévention Laver soigneusement après manipulation.

Réponse EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer.
Si l'irritation oculaire persiste : consulter un médecin.

Stockage/Mise au rebut Éliminer le contenu et/ou le récipient conformément aux réglementations locales, régionales, nationales, et/ou internationales.

2.3 Autres dangers

OSHA HCS 2012 En vertu des réglementations des États-Unis (29 CFR 1910.1200 - Norme de communication des dangers), ce produit n'est pas considéré comme dangereux.

Canada
Selon : WHMIS

2.1 Classification de la substance ou mélange

WHMIS Non classé

2.2 Éléments de l'étiquette

WHMIS Aucune étiquette(s) requise.

2.3 Autres dangers

WHMIS Au Canada, le produit mentionné ci-dessus n'est pas considéré dangereux en vertu du Système d'information sur les matières dangereuses utilisées au travail (SIMDUT).

2.4 Autres informations

Tous les autres réactifs, les billes et autres constituants sont à des concentrations inférieures à 1 % dans le mélange ou ne sont pas considérés dangereux selon la réglementation américaine sur la communication des dangers (29 CFR 1910.1200), selon les directives de l'UE concernant la classification et l'étiquetage des substances et des mélanges, ou selon le système international d'harmonisation pour la classification et l'étiquetage des substances ou des mélanges.

Section 3 : Composition/informations sur les ingrédients

3.1 Substances

La matière ne répond pas aux critères d'une substance.

3.2 Mélanges

Composition					
Nom chimique	**Identifiants**	**%**	**DL50/CL50**	**Classifications selon réglementation/directive**	**Commentaires**
Thiocyanate de guanidinium	**CAS :** 593-84-0 **EINECS :** 209-812-1	10 % - 20 %	593 mg/kg	**EU CLP :** Tox. aiguë 5, H302, H313, H320 **SGH ONU :** Tox. aiguë 5 (voie orale) ; irrit. cutanée 5 ; irrit. yeux 2B **OSHA HCS 2012 :** Tox. aiguë 5 (voie orale) ; irrit. yeux 2B	ADD

Section 4 : Mesures de premier secours

4.1 Description des premiers soins

Inhalation Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. Déplacer la victime à l'air frais. Administrer de l'oxygène si la respiration est difficile. Ne pas faire de bouche-à-bouche si la victime a inhalé la substance ; pratiquer la respiration artificielle à l'aide d'un masque de poche doté d'une valve unidirectionnelle ou d'un autre dispositif médical respiratoire approprié. Pratiquer la respiration artificielle si la victime ne respire pas.

Peau Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact cutané mineur, éviter de répandre la matière sur la peau non affectée. En cas de contact avec la substance, rincer immédiatement la peau à l'eau courante pendant au moins 20 minutes. Retirer et isoler les vêtements contaminés.

Yeux Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact avec la substance, rincer immédiatement les yeux à l'eau courante pendant au moins 20 minutes. Si l'irritation oculaire persiste : consulter un médecin.

Ingestion Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas d'ingestion, rincer la bouche avec de l'eau (seulement si la victime est consciente). NE PAS faire vomir. Ne pas faire de bouche-à-bouche si la victime a ingéré la substance. Consulter immédiatement un médecin en cas d'ingestion.

4.2 Symptômes et effets les plus importants, aigus et différés

Voir la section 11 - Informations toxicologiques.

4.3 Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires

Notes pour le médecin Tous les traitements doivent être basés sur les signes et symptômes de détresse observés chez le patient. Il faut envisager la possibilité d'une surexposition à d'autres matières que ce produit.

Section 5 : Mesures de lutte contre l'incendie

5.1 Agents extincteurs

Agent extincteur convenable	INCENDIES MAJEURS : poudre sèche, CO2, mousse antialcool ou eau pulvérisée. INCENDIES MINEURS : poudre sèche, CO2, ou eau pulvérisée.
Agent extincteur inapproprié	Aucune donnée disponible

5.2 Dangers particuliers résultant de la substance ou du mélange

Dangers inhabituels d'incendie et d'explosion	La cartouche en plastique contenant des réactifs peut émettre des vapeurs toxiques d'oxydes de carbone, d'oxydes de soufre et d'oxydes d'azote.
Produits de combustion dangereux	Aucune donnée disponible

5.3 Conseils aux pompiers

Les vêtements structurels de protection des pompiers fournissent une protection limitée UNIQUEMENT en cas d'incendie ; ils ne sont pas efficaces dans les cas de déversement où le contact direct avec la substance est possible. Porter des vêtements de protection chimique spécifiquement recommandés par le fabricant. Ceux-ci peuvent fournir peu ou pas de protection thermique.
Porter un appareil respiratoire autonome à pression positive (ARA).
INCENDIES MINEURS : enlever les conteneurs de la zone d'incendie si vous pouvez le faire sans risque.

Section 6 : Mesures en cas de fuite accidentelle

6.1 Précautions individuelles, équipement de protection et mesures d'urgence

Précautions individuelles	Dans le cas où une cartouche est percée, ces précautions individuelles s'appliquent. Porter les vêtements de protection appropriés. Ne pas marcher à travers la matière déversée. Ne pas toucher les conteneurs endommagés ou la matière déversée sauf en cas de port de vêtements de protection appropriés. Ventiler les espaces clos.
Mesures d'urgence	Aucune procédure d'urgence ne devrait s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations.

6.2 Précautions environnementales

Prévenir la pénétration dans les cours d'eau, les égouts, les sous-sols ou les endroits confinés.

6.3 Méthodes et matériaux de confinement et de nettoyage

Mesures de confinement/ de nettoyage	Pour les petits déversements, porter des gants et absorber la matière déversée avec une serviette en papier. Ne pas jeter la matière déversée dans les égouts.

6.4 Référence à d'autres sections

Voir la section 8 - Contrôles de l'exposition/Protection individuelle, ainsi que la section 13 - Considérations de mise au rebut.

Section 7 : Manutention et stockage

7.1 Précautions pour une manutention sans danger

Manutention Aucune manipulation spéciale n'est nécessaire. Si une cartouche est percée, éviter tout contact avec les réactifs déversés.

7.2 Conditions de sécurité du stockage, y compris toutes incompatibilités

Stockage Stocker conformément à l'étiquetage des produits. Tenir à l'écart des matières incompatibles. Garder sous clef. Conserver le conteneur/emballage hermétiquement fermé dans un endroit frais et bien aéré.

7.3 Utilisation(s) finale(s) spécifique(s)

Voir la section 1.2 - Utilisations pertinentes identifiées.

Section 8 : Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

	Limites d'exposition/Lignes directrices			
	Résultat	**ACGIH**	**NIOSH**	**OSHA**
Thiocyanate de guanidinium	Moyenne pondérée en fonction du temps (TWA)	Non établi	Non établi	Non établi

8.2 Contrôles d'exposition

Mesures/contrôles techniques Une bonne ventilation générale doit être utilisée. Les débits de ventilation doivent être adaptés aux conditions. Le cas échéant, utiliser des enceintes d'isolement, une ventilation aspirante locale ou d'autres moyens techniques pour maintenir les concentrations atmosphériques en dessous des limites d'exposition recommandées. Si les limites d'exposition n'ont pas été établies, maintenir les concentrations atmosphériques à un niveau acceptable.

Équipement de protection individuelle

Respiratoire Un équipement respiratoire ne devrait pas s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations. Sinon, suivre les réglementations de l'OSHA relatives aux appareils respiratoires définies dans 29 CFR 1910.134 ou la norme européenne EN 149. Utiliser un appareil respiratoire approuvé par le NIOSH/MSHA ou la norme européenne EN 149 si les limites d'exposition sont dépassées ou des symptômes apparaissent.

Yeux/visage Porter des lunettes anti-éclaboussures contre les produits chimiques.

Peau/corps Porter des vêtements de protection

Contrôle d'exposition lié à la protection de 'environnement Suivre les bonnes pratiques pour la gestion de site et l'élimination des déchets.

Clef aux abréviations
OSHA = Administration de la sécurité et de la santé au travail
TWA = Les moyennes pondérées dans le temps sont basées sur des expositions de 8 h/jour, 40 h/semaine

Section 9 : Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques

Description de la matière			
Forme physique	Liquide	Apparence/Description	Les réactifs sont des liquides incolores et limpides, sans odeur, qui sont principalement tamponnés dans des solutions aqueuses.
Couleur	Limpide	Odeur	Inodore
Seuil d'odeur	Manque de données		
Propriétés générales			
Point d'ébullition	100 °C (212 °F)	Point de fusion/Point de congélation	0 °C (32 °F)
Température de décomposition	Manque de données	pH	3,5 à 8,8
Densité spécifique/relative	Manque de données	Solubilité dans l'eau	Manque de données
Viscosité	Manque de données	Propriétés explosives	Manque de données
Propriétés comburantes :	Manque de données		
Volatilité			
Pression de vapeur	Manque de données	Densité de vapeur	Manque de données
Taux d'évaporation	Manque de données		
Inflammabilité			
	182,2222 – 293,3333 °C (360 – 560 °F) (réactif de liaison)	LSE	Manque de données
LIE	Manque de données	Auto-inflammation	Manque de données
Inflammabilité (solide, gaz)	Manque de données		
Environnemental(e)			
Coefficient de partage octanol/eau	Manque de données		

9.2 Autres informations

Aucun paramètre physique ou chimique supplémentaire noté.

Section 10 : Stabilité et réactivité

10.1 Réactivité

Pas de réactions dangereuses connues dans des conditions normales d'utilisation.

10.2 Stabilité chimique

Stable

10.3 Possibilité de réactions dangereuses

Il ne se produira pas de polymérisation dangereuse.

10.4 Situations à éviter

Matières incompatibles. Si l'on brûle une cartouche en plastique contenant des réactifs, des sous-produits toxiques peuvent être libérées.

10.5 Substances incompatibles

Acides, agents oxydants.

10.6 Produits de décomposition dangereux

Si l'on brûle une cartouche en plastique contenant des réactifs, des sous-produits toxiques peuvent être libérées.

Section 11 : Information toxicologique

11.1 Informations sur les effets toxiques

Composants		
Thiocyanate de guanidinium	593-84-0	**Toxicité aiguë :** Voie intrapéritonéale-Souris DL50 593 mg/kg

Propriétés GHS	Classification
Toxicité aiguë	**EU/CLP**•Manque de données **SGH ONU 3**•Toxicité aiguë - voie orale 5 - ETAmix (voie orale) = 2 965 mg/kg **OSHA HCS 2012**•Manque de données
Corrosion/irritation cutanée	**EU/CLP**•Manque de données **SGH ONU 3**•Légère irritation cutanée 3 **OSHA HCS 2012**•Manque de données
Lésion/irritation grave des yeux	**EU/CLP**•Manque de données **SGH ONU 3**•Légère iritation des yeux 2B **OSHA HCS 2012**•Légère iritation des yeux 2B
Sensibilisation cutanée	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Sensibilisation respiratoire	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Danger d'aspiration	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Cancérogénicité	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Mutagénicité de cellule germinale	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Toxicité pour la reproduction	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-SE	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-RE	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données

Effets éventuels sur la santé

Inhalation	
Aigu (immédiat)	Peut provoquer une irritation.
Chronique (différé)	Aucune donnée disponible
Peau	
Aigu (immédiat)	Provoque une irritation de la peau.
Chronique (différé)	Aucune donnée disponible
Yeux	
Aigu (immédiat)	Provoque une irritation des yeux.
Chronique (différé)	Aucune donnée disponible
Ingestion	
Aigu (immédiat)	Nocif en cas d'ingestion.
Chronique (différé)	Aucune donnée disponible

Clef aux abréviations
DL = Dose létale

Section 12 : Information écologique

12.1 Toxicité

CL50 (guppy) : 89,1 mg/l à 96 h

12.2 Persistance et dégradabilité

Manque de données matérielles.

12.3 Potentiel bioaccumulatif

Manque de données matérielles.

12.4 Mobilité dans le sol

Manque de données matérielles.

12.5 Résultats des évaluations PBT et vPvB

Aucune évaluation PBT ou vPvB n'a été réalisée.

12.6 Autres effets nocifs

Aucune étude n'a été trouvée.

Section 13 : Considérations de mise au rebut

13.1 Méthodes de traitement des déchets

Déchets du produit Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

Conditionnement des déchets Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

13.2 Autres informations

Les échantillons biologiques, appareils de transfert et cartouches usagées doivent être considérés comme étant susceptibles de transmettre des agents infectieux exigeant des précautions standard. Suivre les consignes environnementales d'élimination des déchets établies par l'établissement pour l'élimination appropriée des cartouches usagées et des réactifs non utilisés. Ces matériaux peuvent présenter des caractéristiques de déchets chimiques dangereux exigeant des procédures d'élimination spécifiques au niveau national ou régional. En l'absence de directives claires de la réglementation nationale ou régionale sur l'élimination appropriée, les échantillons biologiques et les cartouches usagées doivent être éliminés conformément aux directives de manipulation et d'élimination des déchets médicaux de l'OMS (Organisation Mondiale de la Santé).

Section 14: Informations de transport

	14.1 Numéro ONU	14.2 Nom d'expédition des Nations Unies	14.3 Classe(s) de danger pour le transport	14.4 Groupe d'emballage	14.5 Dangers pour l'environnement
DOT	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet
TDG	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet
IMO/IMDG	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet
IATA/ICAO	Non réglementé	Non réglementé	Non réglementé	Non réglementé	Sans objet

14.6 Précautions spéciales pour l'utilisateur

Rien de précisé.

14.7 Transport en vrac conformément à l'annexe II de la convention Marpol 73/78 et au recueil IBC

Manque de données.

Section 15: Informations réglementaires

15.1 Réglementation relative à la sécurité, la santé et l'environnement/ législation spécifique à la substance ou au mélange

Classifications de dangers SARA Aiguë

Inventaire						
Composant	**CAS**	**LIS du Canada**	**LES du Canada**	**UE EINECS**	**UE ELNICS**	**TSCA**
Thiocyanate de guanidinium	593-84-0	Oui	Non	Oui	Non	Oui

Canada

Travail

Canada - SIMDUT - Classifications des substances

•Thiocyanate de guanidinium	593-84-0	Non énuméré

Canada - SIMDUT - Liste de divulgation des ingrédients

•Thiocyanate de guanidinium	593-84-0	Non énuméré

Environnement

Canada - LCPE - Liste des substances prioritaires

•Thiocyanate de guanidinium	593-84-0	Non énuméré

États-Unis

Travail

É.-U. - OSHA - Gestion de la sécurité des procédés - Produits chimiques très dangereux

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - OSHA - Produits chimiques spécifiquement réglementés

•Thiocyanate de guanidinium	593-84-0	Non énuméré

Environnement

É.-U. - CAA (Clean Air Act) - 1990 Polluants atmosphériques dangereux

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Substances dangereuses et leurs quantités à déclarer

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Radionucléides et leurs quantités à déclarer

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses QR EPCRA

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses TPQ

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Rapports sur les émissions

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Liste des produits chimiques PBT

•Thiocyanate de guanidinium	593-84-0	Non énuméré

États-Unis - Californie

Environnement

É.-U. - Californie - Proposition 65 - Liste des substances cancérigènes

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - Californie - Proposition 65 - Toxicité pour le développement

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - Californie - Proposition 65 - Doses maximales admissibles (MADL)

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - Californie - Proposition 65 - Niveaux de risque non significatifs (NSRL)

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Femme

•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Homme

•Thiocyanate de guanidinium	593-84-0	Non énuméré

15.2 Évaluation de sécurité chimique

Aucune évaluation de sécurité chimique n'a été effectuée.

Section 16: Autres informations

Phrases pertinentes (code et texte entier)

H302 – Nocif en cas d'ingestion
H313 – Peut être nocif par contact cutané
H320 – Provoque une irritation des yeux

Déclaration de non-responsabilité

Les informations ci-dessus reposent sur les données dont nous disposons et que nous jugeons correctes. Dans la mesure où ces informations peuvent être utilisées dans des conditions hors de notre contrôle et que nous ne connaissons pas nécessairement, nous n'assumons aucune responsabilité pour les conséquences de leur utilisation et toutes les personnes recevant le produit doivent en déterminer personnellement les effets, les propriétés, ainsi que les mesures de protection et d'élimination nécessaires en rapport avec leurs conditions d'utilisation particulières. Aucune représentation, garantie ou assurance, explicite ou implicite (y compris une garantie d'aptitude ou de qualité marchande pour un but particulier) n'est faite concernant les produits, l'exactitude des informations, les résultats découlant de leur utilisation ou les risques liés à l'utilisation du produit. Il y a lieu de faire preuve de prudence lors de la manipulation et de l'utilisation du produit. Les informations ci-dessus sont fournies en toute bonne foi et avec la conviction qu'elles sont exactes. À la date de publication, nous fournissons toutes les informations pertinentes pour la manipulation prévisible du produit. Cependant, dans l'éventualité d'un incident associé à l'utilisation de ce produit, cette fiche de données de sécurité ne peut pas (et n'est pas conçue pour) se substituer à l'avis d'un personnel correctement formé.

Clef aux abréviations
ADD = Pas de données disponibles

Sicherheitsdatenblatt
Datum des Inkrafttretens: Mai 2020
Ersetzt (Datum): April 2020

Xpert CT Assay
Xpert CT/NG Assay

Abschnitt 1: Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktname **Xpert CT Assay; Xpert CT/NG Assay**
Produktcode GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Relevante identifizierte Verwendungen der Substanz oder Mischung und Verwendungen, von denen abgeraten wird

Relevante identifizierte Verwendung(en) Laborgebrauch

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Vereinigte Staaten
www.cepheid.com
USA: techsupport@cepheid.com
Telefon (Zentrale) 1 (888) 838-3222 - US Option 2
Telefon (Zentrale) 1 (408) 541-4191 - außerhalb der USA

Lieferant Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Schweden
www.cepheidinternational.com
EU: support@cepheideurope.com
Telefon (Zentrale) 33 563 825 319 - EU

1.4 Notrufnummer

Hersteller 1 (800) 535-5053 - INFOTRAC - 24-Stunden-Notruf
Hersteller 1 (352) 323-3500 - außerhalb der USA

Abschnitt 2: Mögliche Gefahren

EU/EEC

Nach: Verordnung (EG) Nr. 1272/2008 (CLP)/REACH 1907/2006 [geändert durch 453/2010]

2.1 Einstufung des Stoffs oder Gemischs

CLP Das folgende SDB gilt für das Fertiggemisch nur, wenn es im Labor benutzt wird. Das Produkt enthält Kügelchen und Reagenzien, die in der Kartusche oder in separaten Behältern vorhanden sind. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Nicht klassifiziert

2.2 Kennzeichnungselemente

CLP

Gefahrenhinweise	H302 – Gesundheitsschädlich bei Verschlucken H313 – Möglicherweise gesundheitsschädlich bei Hautkontakt H320 – Verursacht Augenreizung
Sicherheitshinweise	
Vorbeugung	P264 – Nach Gebrauch gründlich waschen. P270 – Bei Gebrauch nicht essen, trinken oder rauchen.
Reaktion	P301+P312 – BEI VERSCHLUCKEN: Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen. P330 – Mund ausspülen.
Lagerung/Entsorgung	P501 – Inhalt und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften entsorgen.

2.3 Sonstige Gefahren

CLP	Nach Verordnung (EG) Nr. 1272/2008 (CLP) gilt dieses Material nicht als gefährlich.

UN GHS Revision 3 (Inhalt der auf den Produkten verwendeten Etiketten)

Nach: Global harmonisiertes System der Einstufung und Kennzeichnung von Chemikalien (GHS) der UN: Dritte überarbeitete Auflage

2.1 Einstufung des Stoffs oder Gemischs

UN GHS	Akute Toxizität, oral 5 Leichte Hautreizung 5 Leichte Augenreizung 2B

2.2 Kennzeichnungselemente

UN GHS

WARNHINWEIS

Gefahrenhinweise	Gesundheitsschädlich bei Verschlucken Möglicherweise gesundheitsschädlich bei Hautkontakt Verursacht Augenreizungen
Sicherheitshinweise	
Vorbeugung	Nach Gebrauch gründlich waschen.
Reaktion	Bei Hautreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen.
Lagerung/Entsorgung	Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

2.3 Sonstige Gefahren

UN GHS	Nach dem global harmonisierten System zur Einstufung und Kennzeichnung (GHS) gilt dieses Produkt als gefährlich.

Vereinigte Staaten (VS)
Nach: OSHA 29 CFR 1910.1200 HCS

2.1 Einstufung des Stoffs oder Gemischs

OSHA HCS 2012 Leichte Augenreizung 2B

2.2 Kennzeichnungselemente

OSHA HCS 2012

Gefahrenhinweise Verursacht Augenreizungen

Sicherheitshinweise

Vorbeugung Nach Gebrauch gründlich waschen.

Reaktion BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Lagerung/Entsorgung Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

2.3 Sonstige Gefahren

OSHA HCS 2012 Nach den Vorschriften der USA (29 CFR 1910.1200 - Norm für Gefahrenkommunikation) gilt dieses Produkt nicht als gefährlich.

Kanada
Nach: WHMIS

2.1 Einstufung des Stoffs oder Gemischs

WHMIS Nicht klassifiziert

2.2 Kennzeichnungselemente

WHMIS Kein(e) Beschriftungselement(e) erforderlich.

2.3 Sonstige Gefahren

WHMIS In Kanada ist das oben genannte Produkt nach dem Workplace Hazardous Materials Information System (WHMIS) nicht als gefährlich einzustufen.

2.4 Sonstige Angaben

Alle anderen Reagenzien, Körner und andere Bestandteile sind in Konzentrationen unter 1 % im Gemisch vorhanden oder gelten nicht als gefährlich gemäß den US-Richtlinien für die Gefahrenkommunikation (29 CFR 1910.1200), den EU-Richtlinien für die Einstufung und Etikettierung von Substanzen oder Gemischen oder dem globalen Harmonisierungssystem für die Einstufung und Etikettierung von Substanzen oder Gemischen.

Abschnitt 3: Zusammensetzung/Angaben zu den Bestandteilen

3.1 Stoffe

Material erfüllt nicht die Kriterien einer Substanz.

3.2 Gemische

Zusammensetzung					
Chemische Bezeichnung	**Kennzeichnung**	**%**	**LD50/LC50**	**Klassifizierungen nach der Verordnung/Richtlinie**	**Bemerkungen**
Guanidiniumthiocyanat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10–20 %	593 mg/kg	**EU CLP:** Acute Tox. 5, H302, H313, H320 **UN GHS:** Acute Tox. 5 (Orl); Skin Irrit. 5; Eye Irrit. 2B **OSHA HCS 2012:** Acute Tox. 5 (Orl); Eye Irrit. 2B	KDV

Abschnitt 4: Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Einatmen

Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Verunfallten an die frische Luft bringen. Bei Atemschwierigkeiten Sauerstoffzufuhr einleiten. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat; künstliche Beatmung mit einer mit Einwegventil ausgestatteten Taschen-Sauerstoffmaske oder sonstigem geeigneten medizinischen Beatmungsgerät einleiten. Bei Atemstillstand künstliche Beatmung umgehend einleiten.

Haut

Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei geringem Hautkontakt Material nicht auf andere Hautbereiche verteilen. Im Falle eines Hautkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Verunreinigte Kleidung entfernen und isolieren.

Augen

Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Im Falle eines Augenkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Verschlucken

Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei Einnahme Mund mit Wasser ausspülen (nur, wenn die Person bei Bewusstsein ist). KEIN Erbrechen herbeiführen. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat. Bei Einnahme sofort Arzt zu Rate ziehen.

4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen

Siehe Abschnitt 11 - Toxikologische Informationen.

4.3 Hinweis auf ärztliche Soforthilfe oder Spezialbehandlung

Hinweise für den Arzt

Alle Behandlungsmaßnahmen sollten auf den beobachteten Anzeichen und Symptomen von Erschöpfung beim Patienten basieren. Außerdem ist zu berücksichtigen, dass es möglicherweise zum Kontakt mit anderen Materialien zusätzlich zu diesem Produkt kam.

Abschnitt 5: Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel	GROSSBRAND: Trockenlöschmittel, CO2, alkoholresistenter Schaum oder Wasserstrahl. KLEINBRAND: Trockenlöschmittel, CO2 oder Wasserstrahl.
Ungeeignete Löschmittel	Keine Daten verfügbar

5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren

Ungewöhnliche Brand-und Explosionsgefahren	Die Plastikkartusche enthält Reagenzien, die toxische Kohlenoxid-, Schwefeloxid- und Stickstoffoxiddämpfe abgeben können.
Gefährliche Verbrennungsprodukte	Keine Daten verfügbar

5.3 Hinweise für die Brandbekämpfung

Für die Feuerbekämpfung vorgesehene Standardarbeitsschutzbekleidung bietet einen begrenzten Schutz NUR in Brandfällen; sie ist ineffektiv bei Verschüttungen, wo ein direkter Kontakt mit dem Stoff möglich ist.
Chemikalienschutzbekleidung tragen, die speziell vom Hersteller empfohlen wird. Sie kann wenig oder keinen Thermoschutz bieten.
Umgebungsluftunabhängiges Atemschutzgerät (SCBA) für Überdruckbetrieb tragen.
KLEINBRAND: Behälter aus der Brandzone entfernen, wenn es kein Risiko darstellt.

Abschnitt 6: Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Persönliche Schutzmaßnahmen	Wenn eine Kartusche bricht, dann sind diese persönlichen Vorkehrungen anzuwenden. Entsprechende Schutzkleidung tragen. Nicht durch das verschüttete Material hindurch gehen. Beschädigte Behälter oder verschüttetes Material ohne geeignete Schutzkleidung nicht anfassen. Geschlossene Räume be- oder entlüften.
Sofortmaßnahmen	Es sind keine Notfallmaßnahmen erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird.

6.2 Umweltschutzmaßnahmen

Nicht in Gewässer, die Kanalisation, Keller oder enge Räume gelangen lassen.

6.3 Methoden und Material für Rückhaltung und Reinigung

Maßnahmen zur Rückhaltung/ Reinigung	Bei kleinen Verschüttungen Handschuhe tragen und Verschüttung mit einem Papiertuch aufnehmen. Verschüttetes Material nicht durch den Abfluss entsorgen.

6.4 Verweis auf andere Abschnitte

Siehe Abschnitt 8 - Einwirkungskontrolle/Personenschutz und Abschnitt 13 - Überlegungen zur Entsorgung.

Abschnitt 7: Handhabung und Lagerung

7.1 Schutzmaßnahmen zur sicheren Handhabung

Handhabung Keine spezielle Handhabung notwendig. Wenn eine Kartusche gebrochen ist, dann ist der Kontakt mit verschütteten Reagenzien zu vermeiden.

7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Umweltverträglichkeiten

Lagerung Produkt gemäß der Etikettierung lagern. Von nicht kompatiblem Material fernhalten. Unter Verschluss aufbewahren. Behälter/Verpackung dicht verschlossen an kühlem, gut belüftetem Ort lagern.

7.3 Spezifische Endanwendungen

Siehe Abschnitt 1.2 - Relevante identifizierte Nutzung.

Abschnitt 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstung

8.1 Zu überwachende Parameter

	Expositionsgrenzwerte/Richtlinien			
	Ergebnis	**ACGIH**	**NIOSH**	**OSHA**
Guanidiniumthiocyanat	TWA	Nicht ermittelt	Nicht ermittelt	Nicht ermittelt

8.2 Begrenzung und Überwachung der Exposition

Technische Maßnahmen/ Kontrollen Es ist eine gute allgemeine Belüftung anzuwenden. Die Belüftungszahl sollte den Bedingungen entsprechen. Prozesskammern, lokale Abzugsanlage oder andere technische Kontrollmittel verwenden, um die Konzentration in der Luft unter den empfohlenen Grenzwerten zu halten. Wenn keine Grenzwerte festgelegt wurden, sind die Konzentrationen auf einem akzeptablen Niveau zu halten.

Persönliche Schutzausrüstung

Atemwege Es wird nicht erwartet, dass Atemschutzgeräte erforderlich sind, sofern das Material unter normalen Bedingungen und wie empfohlen benutzt wird. Ansonsten die OSHA-Vorgaben für Atemschutzgeräte aus 29 CFR 1910.134 oder der Europäischen Norm EN 149 befolgen. Nach NIOSH/MSHA oder der europäischen Norm EN 149 zugelassenes Atemschutzgerät benutzen, wenn die Grenzwerte überschritten werden oder Symptome auftreten.

Augen/Gesicht Schutzbrillen gegen Chemikalienspritzer tragen.

Haut/Körper Schutzkleidung tragen

Umweltkontrollmaßnahmen Beste Praktiken bei Bauleitung und Abfallentsorgung anwenden.

Schlüssel für Abkürzungen
OSHA = Agentur für Sicherheit und Gesundheitsschutz am Arbeitsplatz
TWA = Zeitlich gewichtete Mittelwerte basieren auf einer Exposition von 8 Stunden/Tag, 40 Stunden/Woche

Abschnitt 9: Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Materialbeschreibung			
Physische Gestalt	Flüssigkeit	Aussehen/Beschreibung	Die Reagenzien sind klare, farb- und geruchlose Flüssigkeiten, die in wässrigen Lösungen primär gepuffert sind.
Farbe	Klar	Geruch	Geruchlos
Geruchsschwelle	Fehlende Daten		
Allgemeine Eigenschaften			
Siedepunkt	100 °C (212 °F)	Schmelzpunkt/Gefrierpunkt	0 °C (32 °F)
Zersetzungstemperatur	Fehlende Daten	pH	3,5 bis 8,8
Spezifisches Gewicht/Relative Dichte	Fehlende Daten	Wasserlöslichkeit	Fehlende Daten
Viskosität	Fehlende Daten	Explosive Eigenschaften	Fehlende Daten
Oxidationseigenschaften:	Fehlende Daten		
Volatilität			
Dampfdruck	Fehlende Daten	Dampfdichte	Fehlende Daten
Verdunstungsrate	Fehlende Daten		
Entflammbarkeit			
	182,2222 bis 293,3333 °C (360 bis 560 °F) (Bindungsreagenz)	Obere Expositionsgrenze	Fehlende Daten
Untere Expositionsgrenze	Fehlende Daten	Selbstzündung	Fehlende Daten
Entflammbarkeit (Feststoff, Gas)	Fehlende Daten		
Umwelt			
Oktanol/Wasser-Verteilungskoeffizient	Fehlende Daten		

9.2 Sonstige Angaben

Keine zusätzlichen physikalischen und chemischen Parameter vermerkt.

Abschnitt 10: Stabilität und Reaktivität

10.1 Reaktivität

Keine gefährliche Reaktion bekannt unter Bedingungen der normalen Verwendung.

10.2 Chemische Stabilität

Stabil

10.3 Möglichkeit gefährlicher Reaktionen

Eine gefährliche Polymerisierung findet nicht statt.

10.4 Zu vermeidende Bedingungen

Inkompatibles Material. Eine brennende Plastikkartusche, die Reagenzien enthält, kann toxische Nebenprodukte freisetzen.

10.5 Inkompatible Materialien

Säuren, Oxidationsmittel.

10.6 Gefährliche Zersetzungsprodukte

Eine brennende Plastikkartusche, die Reagenzien enthält, kann toxische Nebenprodukte freisetzen.

Abschnitt 11: Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

Bestandteile		
Guanidiniumthiocyanat	593-84-0	**Akute Toxizität:** Intraperitoneal-Maus LD50 593 mg/kg

GHS-Eigenschaften	Klassifizierung
Akute Toxizität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Akute Toxizität - oral 5 - ATEmix (oral) = 2965 mg/kg **OSHA HCS 2012**•Fehlende Daten
Hautätzende Wirkung/Reizung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Leichte Hautreizung 3 **OSHA HCS 2012**•Fehlende Daten
Schwere Augenschäden/Augenreizung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Leichte Augenreizung 2B **OSHA HCS 2012**•Leichte Augenreizung 2B
Hautsensibilisierung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Sensibilisierung der Atemwege	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Aspirationsgefahr	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Karzinogenität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Keimzell-Mutagenität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Reproduktionstoxizität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-SE	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-RE	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

Mögliche gesundheitliche Auswirkungen

Einatmen	
Akut (sofort)	Kann Reizung verursachen.
Chronisch (verzögert)	Keine Daten verfügbar
Haut	
Akut (sofort)	Verursacht Hautreizung.
Chronisch (verzögert)	Keine Daten verfügbar
Augen	
Akut (Sofort)	Verursacht Augenreizungen.
Chronisch (verzögert)	Keine Daten verfügbar
Verschlucken	
Akut (sofort)	Gesundheitsschädlich bei Verschlucken.
Chronisch (verzögert)	Keine Daten verfügbar

Schlüssel für Abkürzungen
LD = Letale Dosierung

Abschnitt 12: Umweltbezogene Angaben

12.1 Toxizität

LC50 (Guppy): 89,1 mg/l; 96 h

12.2 Persistenz und Abbaubarkeit

Materialdaten fehlen.

12.3 Bioakkumulationspotenzial

Materialdaten fehlen.

12.4 Mobilität im Boden

Materialdaten fehlen.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Es wurde keine PBT- oder vPvB-Bewertung durchgeführt.

12.6 Andere schädliche Wirkungen

Es wurden keine Studien gefunden.

Abschnitt 13: Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Produktabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

Verpackungsabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

13.2 Sonstige Angaben

Biologische Proben, Transfervorrichtungen und gebrauchte Kartuschen sind als infektiös anzusehen und mit den üblichen Vorsichtsmaßnahmen zu handhaben. Halten Sie sich bezüglich der angemessenen Entsorgung gebrauchter Kartuschen und nicht verwendeter Reagenzien an die Umweltschutzvorschriften Ihrer Einrichtung. Diese Materialien können chemischen Sondermüll darstellen, der gemäß bestimmten nationalen oder regionalen Vorgehensweisen entsorgt werden muss. Falls die Vorschriften des jeweiligen Landes oder der jeweiligen Region keine klaren Anweisungen zur Entsorgung enthalten, sollten biologische Proben und gebrauchte Kartuschen gemäß den Richtlinien der WHO (Weltgesundheitsorganisation) zur Handhabung und Entsorgung von medizinischen Abfällen entsorgt werden.

Abschnitt 14: Angaben zum Transport

	14.1 UN-Nummer	14.2 Korrekte UN-Bezeichnung des Frachtgutes	14.3 Transportgefahrenklasse(n)	14.4 Verpackungsgruppe	14.5 Umweltrisiken
DOT	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend
TDG	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend
IMO/IMDG	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend
IATA/ICAO	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht reglementiert	Nicht zutreffend

14.6 Besondere Vorsichtsmaßnahmen für den Verwender

Keine Angaben.

14.7 Massengutbeförderung gemäß Anhang II des MARPOL-Übereinkommens 73/78 und gemäß IBC-Code

Fehlende Daten.

Abschnitt 15: Rechtsvorschriften

15.1 Vorschriften zur Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

SARA – Klassifizierung Akutvon Gefahren

Inventar						
Bestandteil	**CAS**	**Kanada DSL**	**Kanada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidiniumthiocyanat	593-84-0	Ja	Nein	Ja	Nein	Ja

Kanada

Arbeit

Kanada - WHMIS - Klassifizierung von Substanzen

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kanada - WHMIS - Kanadische Offenbarungsliste der Inhaltsstoffe (IDL)

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Umwelt

Kanada - CEPA - Liste prioritärer Stoffe

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten

Arbeit

USA - OSHA - Prozesssicherheitsmanagement - Hochgefährliche Chemikalien

• Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - OSHA - Speziell regulierte Chemikalien

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Umwelt

USA - CAA (Clean Air Act) - 1990 Gefährliche Schadstoffe in der Luft

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Gefährliche Stoffe und deren meldepflichtige Mengen

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Radionuklide und ihre berichtspflichtigen Mengen

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302 - Äußerst gefährliche Stoffe EPCRA RQ-Werte

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302 - Äußerst gefährliche Stoffe TPQ-Werte

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 - Emissionsmeldung

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 – Verzeichnis von PBT-Chemikalien

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien

Umwelt

Vereinigte Staaten - Kalifornien - Proposition 65 - Liste der krebserzeugenden Stoffe

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien - Proposition 65 - Entwicklungstoxizität

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien - Proposition 65 - Maximal zulässige Dosierungen (MADL)

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien - Proposition 65 - Ohne Nennenswerte Risiken (NSRL)

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien - Proposition 65 - Weibliche Reproduktionstoxizität

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien - Proposition 65 - Männliche Reproduktionstoxizität

•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

15.2 Stoffsicherheitsbeurteilung

Es wurde keine chemische Sicherheitsanalyse durchgeführt.

Sicherheitsdatenblatt
Datum des Inkrafttretens: Mai 2020
Ersetzt (Datum): April 2020

Xpert CT Assay
Xpert CT/NG Assay

Abschnitt 16: Sonstige Angaben

Relevante Sätze (Code und vollständiger Wortlaut)	H302 – Gesundheitsschädlich bei Verschlucken H313 – Möglicherweise gesundheitsschädlich bei Hautkontakt H320 – Verursacht Augenreizung
Haftungsausschluss/ Haftungshinweis	Die obigen Informationen basieren auf Daten, die uns verfügbar sind und die wir für korrekt halten. Da die Informationen unter Bedingungen angewendet werden können, die außerhalb unserer Kontrolle liegen und mit denen wir möglicherweise nicht vertraut sind, übernehmen wir keine Verantwortung für die Ergebnisse der Nutzung und alle Personen, die sie erhalten, müssen ihre eigenen Festlegungen bezüglich der Wirkungen, Eigenschaften, Schutzmaßnahmen und Entsorgung vornehmen, die zu den jeweiligen Bedingungen gehören. Es wird keine Zusicherung, Gewährleistung oder Garantie, weder in ausdrücklicher noch in implizierter Form (einschließlich einer Garantie für die Eignung oder Handelsüblichkeit), erteilt werden im Hinblick auf die Stoffe, die Genauigkeit dieser Informationen, die Ergebnisse, die aus deren Nutzung resultieren, oder die Gefahren, die mit der Nutzung des Stoffes verbunden sind. Bei der Handhabung und Nutzung des Stoffs ist Vorsicht anzuwenden. Die obigen Informationen wurden nach bestem Wissen angegeben und für akkurat gehalten. Zum Datum der Ausstellung bieten wir alle Informationen, die für die zu erwartende Handhabung des Stoffs relevant sind. Bei einem Vorfall mit diesem Produkt stellt dieses Sicherheitsdatenblatt keinen Ersatz für die Rücksprache mit entsprechend geschultem Personal dar und ist nicht dazu gedacht.

Schlüssel für Abkürzungen
KDV = Keine Daten verfügbar

Scheda dati di sicurezza
Data di decorrenza: Maggio 2020
Assay
Sostituisce la versione del: Aprile 2020

Xpert CT Assay
Xpert CT/NG

Sezione 1: Identificazione della sostanza/miscela e dell'azienda/impresa

1.1 Identificatore del prodotto

Nome prodotto **Xpert CT Assay; Xpert CT/NG Assay**
Codice prodotto GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Usi pertinenti identificati della sostanza o della miscela e utilizzi sconsigliati

Usi pertinenti identificati Uso in laboratorio

1.3 Dettagli del fornitore della scheda dati di sicurezza

Produttore Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Stati Uniti
www.cepheid.com
USA: techsupport@cepheid.com
Telefono (generale) 1 (888) 838-3222 - USA Opzione 2
Telefono (generale) 1 (408) 541-4191 - Fuori dagli USA

Fornitore Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Svezia
www.cepheidinternational.com
UE: support@cepheideurope.com
Telefono (generale) 33 563 825 319 - UE

1.4 Numero telefonico di emergenza

Produttore 1 (800) 535-5053 - INFOTRAC - Numero telefonico di emergenza attivo 24 ore su 24
Produttore 1 (352) 323-3500 - Fuori dagli USA

Sezione 2: Identificazione dei pericoli

UE/CEE

In ottemperanza a: Normativa (CE) N.1272/2008 (CLP)/REACH 1907/2006 [emendata dalla 453/2010]

2.1 Classificazione della sostanza o della miscela

CLP La seguente Scheda informativa in materia di sicurezza (SDS) è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Il prodotto contiene microsfere e reagenti all'interno della cartuccia oppure in contenitori esterni alla cartuccia. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classificato

2.2 Elementi dell'etichetta

CLP

Frasi di rischio	H302 – Nocivo se ingerito H313 – Può essere nocivo per contatto con la pelle H320 – Provoca irritazione oculare
Frasi di prudenza	
Prevenzione	P264 – Lavare accuratamente dopo l'uso. P270 – Non mangiare, né bere, né fumare durante l'uso.
Risposta	P301+P312 – IN CASO DI INGESTIONE accompagnata da malessere: contattare un CENTRO ANTIVELENI o un medico. P330 – Sciacquare la bocca.
Stoccaggio/Smaltimento	P501 – Smaltire il prodotto/recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

2.3 Altri rischi

CLP In base al Regolamento (CE) n. 1272/2008 (CLP), questo materiale non è considerato pericoloso.

UN GHS Revisione 3 (Contenuto delle etichette utilizzate sui prodotti)

In ottemperanza a: Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN Globally Harmonized System of Classification and Labeling of Chemicals, GHS): Revisione della terza edizione

2.1 Classificazione della sostanza o della miscela

UN GHS Tossicità acuta - per via orale 5
Lieve irritazione cutanea 5
Lieve irritazione oculare 2B

2.2 Elementi dell'etichetta

UN GHS

ATTENZIONE

Frasi di rischio	Nocivo se ingerito Può essere nocivo per contatto con la pelle Provoca irritazione oculare
Frasi di prudenza	
Prevenzione	Lavare accuratamente dopo l'uso.
Risposta	In caso di irritazione della pelle: consultare un medico. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. Se l'irritazione degli occhi persiste: consultare un medico. In caso di malessere, contattare un CENTRO ANTIVELENI o un medico.
Stoccaggio/Smaltimento	Smaltire prodotto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

2.3 Altri rischi

UN GHS In conformità al Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN GHS) questo prodotto è considerato pericoloso.

Stati Uniti (USA)
In ottemperanza a: OSHA 29 CFR 1910.1200 HCS

2.1 Classificazione della sostanza o della miscela

OSHA HCS 2012 Lieve irritazione oculare 2B

2.2 Elementi dell'etichetta

OSHA HCS 2012

Frasi di rischio Provoca irritazione oculare

Frasi di prudenza

Prevenzione Lavare accuratamente dopo l'uso.

Risposta IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
Se l'irritazione degli occhi persiste: consultare un medico.

Stoccaggio/Smaltimento Smaltire prodotto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

2.3 Altri rischi

OSHA HCS 2012 Ai sensi della normativa statunitense (29 CFR 1910.1200 - Standard per la comunicazione dei pericoli), questo prodotto non è considerato pericoloso.

Canada
In ottemperanza a: WHMIS

2.1 Classificazione della sostanza o della miscela

WHMIS Non classificato

2.2 Elementi dell'etichetta

WHMIS Non è richiesta alcuna etichetta.

2.3 Altri rischi

WHMIS In Canada, il prodotto di cui sopra non è considerato pericoloso ai sensi del sistema di informazioni sui materiali pericolosi sul luogo di lavoro (Workplace Hazardous Materials Information System, WHMIS).

2.4 Altre informazioni

Tutti gli altri reagenti, le perline e i costituenti hanno concentrazioni inferiori all'1% nella miscela o non sono considerati pericolosi per le normative sulla comunicazione del pericolo degli USA (29 CFR 1910.1200), le direttive UE per la classificazione e l'etichettatura delle sostanze e delle miscele o per il Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche e delle miscele.

Sezione 3: Composizione/Informazioni sugli ingredienti

3.1 Sostanze

Il materiale non soddisfa i criteri di classificazione come sostanza.

3.2 Miscele

Composizione					
Nome Chimico	**Identificatori**	**%**	**DL50/CL50**	**Classificazioni Secondo Regolamento/Direttiva**	**Commenti**
Guanidina tiocianato	**CAS:** 593-84-0 **EINECS:** 209-812-1	10-20%	593 mg/kg	**UE CLP:** Toss. acuta 5, H302, H313, H320 **UN GHS:** Toss. acuta 5 (orale); Irrit. cute 5; Irrit. occhi 2B **OSHA HCS 2012:** Toss. acuta 5 (orale); Irrit. occhi 2B	NDD

Sezione 4: Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Inalazione Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. Portare la persona colpita all'aria aperta. Somministrare ossigeno se la respirazione è difficile. Non usare il metodo bocca-a-bocca se la vittima ha inalato la sostanza; effettuare la respirazione artificiale con l'ausilio di una mascherina con valvola unidirezionale o altro dispositivo medico adeguato. Se la vittima non respira, effettuare la respirazione artificiale.

Cute Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di limitato contatto con la pelle, evitare la dispersione del materiale sulla pelle non interessata. In caso di contatto con la sostanza, sciacquare immediatamente la pelle con acqua corrente per almeno 20 minuti. Rimuovere e isolare gli indumenti contaminati.

Occhi Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di contatto con la sostanza, sciacquare immediatamente gli occhi con acqua corrente per almeno 20 minuti. Se l'irritazione degli occhi persiste: consultare un medico.

Ingestione Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di ingestione, sciacquare la bocca con acqua (solamente se l'infortunato è cosciente). NON provocare il vomito. Non usare il metodo bocca-a-bocca se la vittima ha ingerito la sostanza. In caso di ingestione consultare immediatamente il medico.

4.2 Sintomi ed effetti più importanti, acuti e ritardati

Consultare la Sezione 11 - Informazioni tossicologiche.

4.3 Indicazione delle attenzioni mediche immediate e dei trattamenti speciali necessari

Note per il medico Tutte le cure dovrebbero basarsi sull'osservazione di segni e sintomi di malessere nel paziente. Dovrebbe essere presa in considerazione la possibilità di sovraesposizione a materiali diversi da questo prodotto.

Sezione 5: Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione adeguati	INCENDI DI AMPIE DIMENSIONI: composto chimico secco, CO2, schiumogeno resistente all'alcol o getto d'acqua. INCENDI DI DIMENSIONI RIDOTTE: composto chimico secco, CO2 o getto d'acqua.
Mezzi di estinzione non adeguati	Nessun dato disponibile

5.2 Rischi speciali che scaturiscono dalla sostanza o dalla miscela

Rischi di esplosione e incendi inconsueti	La cartuccia in plastica contenente i reagenti può emettere vapori tossici di ossidi di carbonio, ossidi di zolfo, ossidi di azoto.
Prodotti di combustione pericolosi	Nessun dato disponibile

5.3 Consiglio per i vigili del fuoco

Gli indumenti antincendio strutturali forniscono una protezione limitata SOLO in condizioni di incendio; non sono efficaci in condizioni di fuoriuscite in cui è probabile il contatto diretto con la sostanza.
Indossare abbigliamento protettivo contro gli agenti chimici specificatamente raccomandato dal produttore. Potrebbe fornire limitata o nessuna protezione termica.
Indossare un apparato di respirazione autonomo funzionante a pressione positiva (self-contained breathing apparatus, SCBA).
INCENDI DI DIMENSIONI RIDOTTE: Spostare i contenitori dall'area colpita dall'incendio se non comporta alcun rischio.

Sezione 6: Misure contro il versamento accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure di emergenza

Precauzioni personali	Nel caso in cui si rompa una cartuccia, è possibile applicare queste precauzioni personali. Usare indumenti protettivi adatti. Non camminare sul materiale versato. Toccare i contenitori danneggiati o il materiale versato solo dopo aver indossato l'abbigliamento protettivo adeguato. Ventilare le aree chiuse.
Procedure di emergenza	Non si prevede la necessità di procedure di emergenza se il materiale viene utilizzato in condizioni normali come raccomandato.

6.2 Precauzioni ambientali

Evitare l'ingresso in corsi d'acqua, fognature, seminterrati o aree confinate.

6.3 Metodi e materiali per il contenimento e la pulizia

Misure di contenimento/ pulizia	Per piccole fuoriuscite, indossare guanti e assorbire la fuoriuscita con un tovagliolo di carta. Non gettare il materiale fuoriuscito nei tubi di scarico.

6.4 Riferimento ad altre sezioni

Consultare la Sezione 8 - Controlli dell'esposizione / Protezione personale e la Sezione 13 - Considerazioni per lo smaltimento.

Sezione 7: Manipolazione e stoccaggio

7.1 Precauzioni per la manipolazione sicura

Manipolazione Non è necessario nessun trattamento speciale. Nel caso in cui si rompa una cartuccia, evitare il contatto con i reagenti fuoriusciti.

7.2 Condizioni per lo stoccaggio sicuro, incompatibilità eventuali incluse

Stoccaggio Conservare secondo le indicazioni presenti sull'etichetta del prodotto. Tenere lontano dai materiali incompatibili. Conservare sotto chiave. Conservare il recipiente/ contenitore ben chiuso in luogo fresco e ben ventilato.

7.3 Usi finali specifici

Consultare la Sezione 1.2 - Usi pertinenti identificati.

Sezione 8: Controlli di esposizione / Protezione personale

8.1 Parametri di controllo

	Limiti di Esposizione / Linee Guida			
	Risultato	**ACGIH**	**NIOSH**	**OSHA**
Tiocianato di guanidinio	TWA	Non stabilito	Non stabilito	Non stabilito

8.2 Controlli di esposizione

Misure/Controlli tecnici Garantire una ventilazione generale adeguata. I regimi di ventilazione devono essere adeguati alle condizioni. Se applicabile, utilizzare camere di protezione dei processi, impianti di ventilazione locale o altri controlli tecnici per mantenere i livelli di contaminanti aerei al di sotto dei limiti di esposizione raccomandati. Qualora i limiti di esposizione non fossero stati stabiliti, mantenere i contaminanti aerei a un livello accettabile.

Dispositivi di protezione individuale

Respirazione Non si prevede la necessità di attrezzatura respiratoria se il materiale viene utilizzato in condizioni normali come consigliato. Altrimenti, attenersi alle indicazioni del respiratore OSHA disponibili in 29 CFR 1910.134 o nella norma europea EN 149. In caso di superamento dei limiti di esposizione o manifestazione di sintomi, usare un respiratore approvato da NIOSH/MSHA o dalla norma europea EN 149.

Occhi/Volto Indossare occhiali protettivi per sostanze chimiche.

Pelle/Corpo Indossare indumenti protettivi.

Controlli dell'esposizione ambientale Seguire le migliori pratiche per la gestione del sito e per lo smaltimento dei rifiuti.

Legenda delle abbreviazioni
OSHA = Occupational Safety and Health Administration (Agenzia per la salute e la sicurezza sul lavoro)
TWA = Time-Weighted Averages (Medie pesate nel tempo) basate su esposizioni da 8 ore/giorno, 40 ore/settimana

Sezione 9: Proprietà chimico-fisiche

9.1 Informazioni sulle proprietà chimico-fisiche

Descrizione del materiale			
Forma fisica	Liquido	Aspetto/Descrizione	I reagenti sono liquidi inodori, trasparenti e incolori, che vengono stabilizzati principalmente in soluzioni acquose.
Colore	Trasparente	Odore	Inodore
Soglia di odore	Dati mancanti		
Proprietà generali			
Punto di ebollizione	100 °C (212 °F)	Punto di fusione/Punto di congelamento	0 °C (32 °F)
Temperatura di decomposizione	Dati mancanti	pH	Da 3,5 a 8,8
Gravità specifica/densità relativa	Dati mancanti	Solubilità in acqua	Dati mancanti
Viscosità	Dati mancanti	Proprietà esplosive	Dati mancanti
Proprietà ossidanti:	Dati mancanti		
Volatilità			
Pressione di vapore	Dati mancanti	Densità del vapore	Dati mancanti
Tasso di evaporazione	Dati mancanti		
Infiammabilità			
	Da 182,2222 °C a 293,3333 °C (da 360 °F a 560 °F) (reagente legante)	UEL	Dati mancanti
LEL	Dati mancanti	Autoaccensione	Dati mancanti
Infiammabilità (solido, gas)	Dati mancanti		
Ambientali			
Coefficiente di ripartizione ottanolo-acqua	Dati mancanti		

9.2 Altre informazioni

Non sono state osservate altre proprietà chimico-fisiche.

Sezione 10: Stabilità e reattività

10.1 Reattività

Nessuna reazione pericolosa nota nelle normali condizioni di utilizzo.

10.2 Stabilità chimica

Stabile

10.3 Possibilità di reazioni pericolose

Non si verificherà polimerizzazione pericolosa.

10.4 Condizioni da evitare

Materiali incompatibili. La combustione della cartuccia in plastica contenente i reagenti può liberare sottoprodotti tossici.

10.5 Materiali incompatibili

Acidi, agenti ossidanti.

10.6 Prodotti di decomposizione pericolosi

La combustione della cartuccia in plastica contenente i reagenti può liberare sottoprodotti tossici.

Sezione 11: Informazioni tossicologiche

11.1 Informazioni sugli effetti tossicologici

Componenti		
Tiocianato di guanidinio	593-84-0	**Tossicità acuta:** Intraperitoneale-Topo LD50 593 mg/kg

Proprietà GHS	**Classificazione**
Tossicità acuta	**UE/CLP**•Dati mancanti **UN GHS 3**•Tossicità acuta - Orale 5 - ATEmix (orale) = 2965 mg/kg **OSHA HCS 2012**•Dati mancanti
Corrosione/Irritazione cutanea	**UE/CLP**•Dati mancanti **UN GHS 3**•Lieve irritazione cutanea 3 **OSHA HCS 2012**•Dati mancanti
Grave irritazione/danno oculare	**UE/CLP**•Dati mancanti **UN GHS 3**•Lieve irritazione oculare 2B **OSHA HCS 2012**•Lieve irritazione oculare 2B
Sensibilizzazione cutanea	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Sensibilizzazione respiratoria	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Pericolo derivante dall'inalazione	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Cancerogenicità	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Mutagenesi delle cellule embrionali	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Tossicità per la riproduzione	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-SE	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-RE	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti

Potenziali effetti sulla salute

Inalazione
Acuto (immediato) Può causare irritazione.
Cronico (ritardato) Nessun dato disponibile
Cute
Acuto (immediato) Provoca irritazione cutanea.
Cronico (ritardato) Nessun dato disponibile
Occhi
Acuto (immediato) Provoca irritazione oculare.
Cronico (ritardato) Nessun dato disponibile
Ingestione
Acuto (immediato) Nocivo se ingerito.
Cronico (ritardato) Nessun dato disponibile

Legenda delle abbreviazioni
LD = dose letale

Sezione 12: Informazioni ecologiche

12.1 Tossicità

LC50 (guppy): 89,1 mg/l a 96 h

12.2 Persistenza e degradabilità

Dati materiale mancanti.

12.3 Potenziale di bioaccumulo

Dati materiale mancanti.

12.4 Mobilità nel suolo

Dati materiale mancanti.

12.5 Risultati della valutazione PBT e vPvB

Non sono state condotte valutazioni PBT e vPvB.

12.6 Altri effetti avversi

Non sono stati trovati studi.

Sezione 13: Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti del prodotto Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

Rifiuti di imballaggio Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

13.2 Altre informazioni

I campioni biologici di analisi, i dispositivi di trasferimento e le cartucce usate devono essere trattati come potenziali veicoli di agenti infettivi adottando le precauzioni standard. Attenersi alle procedure di smaltimento dei rifiuti ambientali della propria struttura sanitaria per il corretto smaltimento delle cartucce usate e dei reagenti non utilizzati. Questi materiali potrebbero essere considerati rifiuti chimici pericolosi per il cui smaltimento sarà necessario attenersi a specifiche procedure nazionali o regionali. Se i regolamenti nazionali o regionali non forniscono istruzioni chiare sul corretto smaltimento, i campioni biologici di analisi e le cartucce usate devono essere smaltiti in base alle linee guida dell'OMS (Organizzazione mondiale della sanità) sulla manipolazione e lo smaltimento dei rifiuti medici.

Sezione 14: Informazioni sul trasporto

	14.1 Numero ONU	14.2 Nome di spedizione corretto ONU	14.3 Classi di pericolosità per il trasporto	14.4 Gruppo di imballaggio	14.5 Pericoli ambientali
DOT	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile
TDG	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile
IMO/IMDG	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile
IATA/ICAO	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non soggetto a regolamentazione	Non applicabile

14.6 Precauzioni speciali per l'utilizzatore

Nessuna specificata.

14.7 Trasporto alla rinfusa in conformità all'Allegato II di MARPOL 73/78 e al codice IBC

Dati mancanti.

Sezione 15: Informazioni regolatorie

15.1 Normative/legislazione in materia di ambiente, salute e sicurezza specifiche per la sostanza o la miscela

Classificazioni dei rischi SARA Acuta

Inventario						
Componente	**CAS**	**Canada DSL**	**Canada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Tiocianato di guanidinio	593-84-0	Sì	No	Sì	No	Sì

Canada

Lavoro

Canada - WHMIS - Classificazione delle sostanze

•Tiocianato di guanidinio	593-84-0	Non elencato

Canada - WHMIS - Elenco degli ingredienti

•Tiocianato di guanidinio	593-84-0	Non elencato

Ambiente

Canada - CEPA - Elenco sostanze prioritarie

•Tiocianato di guanidinio	593-84-0	Non elencato

Stati Uniti

Lavoro

USA - OSHA - Gestione dei processi di sicurezza - Sostanze chimiche estremamente pericolose

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - OSHA - Prodotti chimici specificamente regolati

•Tiocianato di guanidinio	593-84-0	Non elencato

Ambiente

USA - CAA (Clean Air Act) - 1990 Inquinanti pericolosi per l'aria

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - CERCLA/SARA - Sostanze pericolose e quantità riportabili

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - CERCLA/SARA - Radionuclidi e quantità riportabili

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose EPCRA RQ

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose TPQ

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - CERCLA/SARA - Sezione 313 - Rapporto sulle emissioni

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - CERCLA/SARA - Sezione 313 - Certificazione chimica PBT

•Tiocianato di guanidinio	593-84-0	Non elencato

Stati Uniti - California

Ambiente

USA - California - Proposta 65 - Elenco sostanze cancerogene

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - California - Proposta 65 - Tossicità dello sviluppo

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - California - Proposta 65 - MADL (Maximum Allowable Dose Levels, livelli di dose massimi consentiti)

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - California - Proposta 65 - NSRL (No Significant Risk Levels, nessun livello di rischio significativo)

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - California - Proposta 65 - Tossicità sulla riproduzione - Femminile

•Tiocianato di guanidinio	593-84-0	Non elencato

USA - California - Proposta 65 - Tossicità sulla riproduzione - Maschile

•Tiocianato di guanidinio	593-84-0	Non elencato

15.2 Valutazione della sicurezza chimica

Non è stata eseguita alcuna valutazione della sicurezza chimica.

Sezione 16: Altre informazioni

Frasi pertinenti (codice e testo completo)	H302 – Nocivo se ingerito H313 – Può essere nocivo per contatto con la pelle H320 – Provoca irritazione oculare
Esclusione/Dichiarazione di responsabilità	Le suddette informazioni si basano su dati a nostra disposizione e ritenuti corretti. Poiché le informazioni possono essere applicate in condizioni che vanno oltre il nostro controllo e che potremmo non conoscere bene, non ci assumiamo nessuna responsabilità per i risultati derivanti dall'uso che ne viene fatto, e tutte le persone che ne usufruiranno devono stabilire gli effetti, le proprietà, le protezioni e lo smaltimento riguardanti ogni singola situazione. Nessuna rappresentazione, garanzia o assicurazione, esplicita o implicita (comprese una garanzia di idoneità o commerciabilità per un particolare scopo), viene fatta per quanto riguarda i materiali, la precisione delle informazioni fornite, i risultati ottenibili dall'uso che ne viene fatto, o i pericoli connessi con l'uso del materiale. L'uso e la manipolazione del materiale devono essere eseguiti con attenzione. Le suddette informazioni sono fornite in buona fede e con la convinzione che siano esatte. A partire dalla data di emissione, vengono fornite tutte le informazioni a disposizione relativamente al trattamento prevedibile del materiale. Tuttavia, in caso di un incidente avverso relativo al prodotto, questa scheda dati di sicurezza non è, e non intende essere, il surrogato della consultazione con personale opportunamente addestrato.

Legenda delle abbreviazioni
NDD = Nessun dato disponibile

Ficha de datos de seguridad
Fecha de entrada en vigor: Mayo de 2020
Sustituye a fecha: Abril 2020

Xpert CT Assay
Xpert CT/NG Assay

Sección 1 – Identificación de la sustancia/mezcla y del proyecto/empresa

1.1 Identificador del producto

Nombre del producto **Xpert CT Assay; Xpert CT/NG Assay**
Código del producto GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Usos identificados de la sustancia o mezcla y usos no recomendados

Usos identificados Uso en laboratorio

1.3 Detalles del proveedor de la ficha de datos de seguridad

Fabricante Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Estados Unidos
www.cepheid.com
EE. UU.: techsupport@cepheid.com
Teléfono (general) 1 (888) 838-3222 - EE. UU. (opción 2)
Teléfono (general) 1 (408) 541-4191 - Fuera de EE. UU.

Proveedor Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Suecia
www.cepheidinternational.com
UE: support@cepheideurope.com
Teléfono (general) 33 563 825 319 - UE

1.4 Número de teléfono de emergencia

Fabricante 1 (800) 535-5053 - INFOTRAC - Emergencia (24 h)
Fabricante 1 (352) 323-3500 - Fuera de EE. UU.

Sección 2 – Identificación de riesgos

UE/CEE

De acuerdo con: Reglamento (CE) Nº 1272/2008 (CLP)/REACH 1907/2006 [modificado por 453/2010]

2.1 Clasificación de la sustancia o mezcla

CLP La siguiente FDS está destinada exclusivamente al uso en laboratorio del producto de la mezcla final acabado. El producto contiene microesferas y reactivos en el cartucho o en los contenedores externos. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
No clasificado

2.2 Elementos de la etiqueta

CLP

Declaraciones de riesgo	H302 - Nocivo en caso de ingestión H313 - Puede ser nocivo en contacto con la piel H320 - Provoca irritación ocular
Declaraciones de precaución	
Prevención	P264 - Lavarse concienzudamente tras la manipulación. P270 - No comer, beber ni fumar durante su utilización.
Respuesta	P301+P312 - EN CASO DE INGESTIÓN: Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico si se encuentra mal. P330 - Enjuagarse la boca.
Almacenamiento/eliminación	P501 - Eliminar el contenido/el recipiente en conformidad con los reglamentos locales, regionales, nacionales e internacionales.

2.3 Otros riesgos

CLP	De acuerdo con el Reglamento (CE) Nº 1272/2008 (CLP), este material no se considera peligroso.

SGA de la ONU, revisión 3 (Contenido del etiquetado utilizado en los productos)

De acuerdo con: Sistema Globalmente Armonizado (SGA) de Clasificación y Etiquetado de Productos Químicos de la ONU: Tercera edición revisada

2.1 Clasificación de la sustancia o mezcla

SGA de la ONU	Toxicidad oral aguda 5 Irritación dérmica leve 5 Irritación ocular leve 2B

2.2 Elementos de la etiqueta

SGA de la ONU

ADVERTENCIA

Declaraciones de riesgo	Nocivo en caso de ingestión Puede ser nocivo en contacto con la piel Provoca irritación ocular
Declaraciones preventivas	
Prevención	Lavarse concienzudamente tras la manipulación.
Respuesta	En caso de irritación cutánea: Consultar a un médico. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. Si persiste la irritación ocular: Consultar a un médico. Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico en caso de malestar.
Almacenamiento/eliminación	Eliminar el contenido/el recipiente en conformidad con los reglamentos locales, regionales, nacionales e internacionales.

2.3 Otros riesgos

SGA de la ONU — De acuerdo con el Sistema Globalmente Armonizado de Clasificación y Etiquetado de Productos Químicos (SGA), este producto se considera peligroso.

Estados Unidos (EE. UU.)
De acuerdo con: OSHA 29 CFR 1910.1200 HCS

2.1 Clasificación de la sustancia o mezcla

HCS 2012 de la OSHA — Irritación ocular leve 2B

2.2 Elementos de la etiqueta

HCS 2012 de la OSHA

Declaraciones de riesgo	Causa irritación ocular
Declaraciones preventivas	
Prevención	Lavarse concienzudamente tras la manipulación.
Respuesta	EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. Si persiste la irritación ocular: Consultar a un médico.
Almacenamiento/eliminación	Eliminar el contenido/el recipiente en conformidad con los reglamentos locales, regionales, nacionales e internacionales.

2.3 Otros riesgos

HCS 2012 de la OSHA — De acuerdo con el reglamento de los Estados Unidos (29 CFR 1910.1200 - Estándar de Comunicación de Riesgos), este producto no se considera peligroso.

Canadá
De acuerdo con: WHMIS

2.1 Clasificación de la sustancia o mezcla

WHMIS — No clasificado

2.2 Elementos de la etiqueta

WHMIS — No se requieren elementos de etiquetado.

2.3 Otros riesgos

WHMIS — El producto mencionado no se considera peligroso en Canadá, de acuerdo con el Sistema de Información de Materiales Peligrosos en el Lugar de Trabajo (WHMIS).

2.4 Información adicional

Todos los demás reactivos, microesferas y otros constituyentes presentan concentraciones inferiores al 1% en la mezcla y no se consideran peligrosos según los reglamentos de comunicación de riesgos de EE. UU. (29 CFR 1910.1200), las directivas para la clasificación y el etiquetado de sustancias y mezclas de la UE y el Sistema Globalmente Armonizado de clasificación y etiquetado de sustancias y mezclas.

Sección 3 – Composición/información de los ingredientes

3.1 Sustancias

El material no cumple con los criterios de clasificación de sustancias.

3.2 Mezclas

Composición					
Nombre del producto químico	**Identificadores**	**%**	**LD50/LC50**	**Clasificaciones de acuerdo con el reglamento/directiva**	**Comentarios**
Tiocianato de guanidina	**CAS:** 593-84-0 **EINECS:** 209-812-1	10 % - 20 %	593 mg/kg	**CLP UE:** Tox. aguda 5, H302, H313, H320 **SGA de la ONU:** Tox. aguda 5 (oral); Irrit. cutánea 5; Irrit. ocular 2B **HCS 2012 de la OSHA:** Tox. aguda 5 (oral); Irrit. ocular 2B	No hay datos disponibles

Sección 4 – Medidas de primeros auxilios

4.1 Descripción de las medidas de primeros auxilios

Inhalación No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Traslade a la persona al aire libre. Si la respiración resulta difícil, administre oxígeno. No utilice el método de boca a boca si la víctima ha inhalado la sustancia; proporcione respiración artificial con la ayuda de una máscara de bolsillo equipada con una válvula de una sola vía u otro dispositivo médico de respiración adecuado. Si la persona no respira, proporcione respiración artificial.

Piel No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Ante un contacto menor con la piel, evite la difusión del material sobre la piel no afectada. Si entra en contacto con la sustancia, enjuague inmediatamente la piel con agua durante al menos 20 minutos. Retire y aísle la ropa contaminada.

Ojo No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Si entra en contacto con la sustancia, enjuague inmediatamente los ojos con agua durante al menos 20 minutos. Si persiste la irritación ocular: Consultar a un médico.

Ingestión No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. En caso de ingestión, enjuague la boca con agua (solo si la persona está consciente). NO provoque el vómito. No utilice el método de boca a boca si la víctima ha ingerido la sustancia. En caso de ingestión, solicite atención médica inmediatamente.

4.2 Síntomas y efectos más importantes, tanto agudos como retardados

Consulte la Sección 11 - Información toxicológica.

4.3 Indicación de cualquier atención médica inmediata y tratamiento especial necesarios

Notas para el médico Todos los tratamientos deben basarse en señales y síntomas observados en el paciente. Considere si puede haberse producido una sobreexposición a otros materiales distintos de este producto.

Sección 5 – Medidas antiincendios

5.1 Medios de extinción

Medios de extinción adecuados	INCENDIOS MAYORES: Polvo químico seco, CO2, espuma resistente al alcohol o agua pulverizada. INCENDIOS MENORES: Polvo químico seco, CO2 o agua pulverizada.
Medios de extinción inadecuados	No hay datos disponibles

5.2 Riesgos especiales procedentes de la sustancia o mezcla

Riesgos de incendio y explosión inusuales	El cartucho de plástico que contiene reactivos puede emitir vapores tóxicos de óxidos de carbono, óxidos de azufre y óxidos de nitrógeno.
Productos de combustión peligrosa	No hay datos disponibles

5.3 Consejos para el personal antiincendios

El traje de protección estándar del personal antiincendios proporciona protección limitada EXCLUSIVAMENTE contra el fuego; no resulta efectivo ante vertidos donde es posible el contacto directo con la sustancia.
Utilice un traje de protección química específicamente recomendado por el fabricante. Puede proporcionar poca o ninguna protección térmica.
Utilice un equipo de respiración autónomo (ERA) de presión positiva.
INCENDIOS MENORES: Mueva los contenedores del área del incendio si la operación no conlleva riesgos.

Sección 6 – Medidas en caso de liberación accidental

6.1 Precauciones personales, equipamiento protector y procedimientos de emergencia

Precauciones personales	En caso de romperse un cartucho, pueden aplicarse estas precauciones personales. Utilice un traje de protección adecuado. No camine a través del material vertido. No toque los contenedores dañados ni los materiales vertidos a menos que utilice un traje de protección adecuado. Ventile las áreas cerradas.
Procedimientos de emergencia	Se espera que no sea necesario aplicar procedimientos de emergencia si el material se utiliza bajo condiciones normales y del modo recomendado.

6.2 Precauciones medioambientales

Evite la entrada en alcantarillas, vías fluviales, sótanos y espacios cerrados.

6.3 Métodos y materiales de contención y limpieza

Medidas de contención/limpieza	Para vertidos menores, utilice guantes y absorba el vertido con una toalla de papel. No deseche materiales vertidos por el desagüe.

6.4 Referencia a otras secciones

Consulte la Sección 8 - Controles de exposición/protección personal y la Sección 13 - Consideraciones de eliminación.

Sección 7 – Manipulación y almacenamiento

7.1 Precauciones para la manipulación segura

Manipulación No se necesita ninguna manipulación especial. En caso de romperse un cartucho, evite el contacto con los reactivos vertidos.

7.2 Condiciones para el almacenamiento seguro, incluidas posibles incompatibilidades

Almacenamiento Almacénelos de acuerdo con las indicaciones de su etiqueta. Mantenga el producto alejado de materiales incompatibles. Guardar bajo llave. Mantenga el contenedor/ embalaje bien cerrado en un lugar fresco y ventilado.

7.3 Usos finales específicos

Consulte la Sección 1.2 - Usos identificados relevantes.

Sección 8 – Controles de exposición / protección personal

8.1 Parámetros de control

	Directrices/límites de exposición			
	Resultado	**ACGIH**	**NIOSH**	**OSHA**
Tiocianato de guanidinio	TWA	No establecido	No establecido	No establecido

8.2 Controles de exposición

Controles/medidas de ingeniería Es necesaria una buena ventilación general. La tasa de ventilación debe corresponder a las condiciones. Si es posible, utilice recintos de procesamiento, ventilación local u otros controles de ingeniería para mantener los niveles del aire por debajo de los límites de exposición recomendados. Si los límites de exposición no se han establecido, mantenga los niveles del aire a un nivel aceptable.

Equipo de protección individual

Respiratorios No se prevé la necesidad de disponer de equipo respiratorio si el material se utiliza en condiciones normales y de la forma recomendada. De lo contrario, siga los reglamentos para máscaras de la OSHA incluidas en el estándar 29 CFR 1910.134 o en el estándar europeo EN 149. Utilice una máscara aprobada por la NIOSH/MSHA o la norma europea EN 149 si se superan los límites de exposición o se experimentan síntomas.

Ocular/facial Utilice gafas de protección contra salpicaduras químicas.

Piel/cuerpo Utilice un traje de protección

Controles de exposición en el medio ambiente Siga las buenas prácticas para administrar el centro y eliminar residuos.

Clave de abreviaturas
OSHA = Administración de Seguridad y Salud Ocupacional
TWA = Los promedios de tiempo ponderado se basan en exposiciones durante 8 h/día y 40 h/semana

Sección 9 – Propiedades físicas y químicas

9.1 Información sobre las propiedades físicas y químicas

Descripción del material			
Forma física	Líquido	Aspecto/Descripción	Los reactivos son líquidos transparentes, incoloros e inodoros, que se tamponan principalmente en soluciones acuosas.
Color	Transparente	Olor	Inodoro
Umbral de olor	Faltan datos		
Propiedades generales			
Punto de ebullición	100 °C (212 °F)	Punto de fusión / punto de congelación	0 °C (32 °F)
Temperatura de descomposición	Faltan datos	pH	3,5 a 8,8
Gravedad específica / densidad relativa	Faltan datos	Hidrosolubilidad	Faltan datos
Viscosidad	Faltan datos	Propiedades explosivas	Faltan datos
Propiedades oxidantes:	Faltan datos		
Volatilidad			
Presión del vapor	Faltan datos	Densidad del vapor	Faltan datos
Tasa de evaporación	Faltan datos		
Inflamabilidad			
	182,2222 a 293,3333 °C (360 a 560 °F) (Reactivo ligante)	UEL	Faltan datos
LEL	Faltan datos	Autoignición	Faltan datos
Inflamabilidad (sólido, gas)	Faltan datos		
Medioambiental			
Coeficiente de reparto octanol/agua	Faltan datos		

9.2 Información adicional

No se han anotado parámetros físicos o químicos adicionales.

Sección 10 – Estabilidad y reactividad

10.1 Reactividad

No se conocen reacciones peligrosas bajo condiciones normales de uso.

10.2 Estabilidad del producto químico

Estable

10.3 Posibilidad de reacciones peligrosas

No ocurrirá polimerización peligrosa.

10.4 Condiciones que deben evitarse

Materiales incompatibles. El cartucho de plástico quemado que contiene reactivos puede liberar subproductos tóxicos.

10.5 Materiales incompatibles

Ácidos, agentes oxidantes.

10.6 Productos de descomposición peligrosos

El cartucho de plástico quemado que contiene reactivos puede liberar subproductos tóxicos.

Sección 11 – Información toxicológica

11.1 Información sobre efectos toxicológicos

Componentes		
Tiocianato de guanidinio	593-84-0	**Toxicidad aguda:** Intraperitoneal-Ratón LD50 593 mg/kg

Propiedades del SGA	Clasificación
Toxicidad aguda	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Toxicidad aguda - Oral 5 - ATEmix (oral) = 2965 mg/kg **HCS 2012 de la OSHA**•Faltan datos
Corrosión/irritación dérmica	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Irritación dérmica leve 3 **HCS 2012 de la OSHA**•Faltan datos
Daño/irritación ocular grave	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Irritación ocular leve 2B **HCS 2012 de la OSHA**•Irritación ocular leve 2B
Sensibilización dérmica	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Sensibilización respiratoria	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Riesgo de aspiración	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Carcinogenicidad	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Mutagenicidad de células germinales	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Toxicidad para la reproducción	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-SE	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-RE	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos

Efectos potenciales en la salud

Inhalación	
Agudo (inmediato)	Puede causar irritación.
Crónico (retardado)	No hay datos disponibles
Piel	
Agudo (inmediato)	Provoca irritación cutánea.
Crónico (retardado)	No hay datos disponibles
Ojo	
Agudo (inmediato)	Causa irritación ocular.
Crónico (retardado)	No hay datos disponibles
Ingestión	
Agudo (inmediato)	Nocivo en caso de ingestión.
Crónico (retardado)	No hay datos disponibles

Clave de abreviaturas
LD = Dosis letal

Sección 12 – Información ecológica

12.1 Toxicidad

LC50 (guppy): 89,1 mg/l a 96 h

12.2 Persistencia y degradabilidad

Faltan datos de material.

12.3 Potencial bioacumulativo

Faltan datos de material.

12.4 Movilidad en el suelo

Faltan datos de material.

12.5 Resultados de la evaluación de PBT y mPmB

No se ha realizado ninguna valoración de PBT y mPmB.

12.6 Otros efectos adversos

No se han encontrado estudios.

Sección 13 – Consideraciones sobre la eliminación

13.1 Métodos de tratamiento de residuos

Residuos de productos Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

Residuos de embalaje Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

13.2 Información adicional

Las muestras biológicas, los dispositivos de transferencia y los cartuchos usados deben ser considerados capaces de transmitir agentes infecciosos que requieren las precauciones habituales. Siga los procedimientos de eliminación de desechos de su centro para la eliminación adecuada de los cartuchos usados y los reactivos no utilizados. Estos materiales pueden presentar características propias de los residuos químicos peligrosos, que requieren procedimientos específicos de eliminación de carácter nacional o regional. Si las normativas nacionales o regionales no proporcionan instrucciones claras en cuanto a los procedimientos de eliminación adecuados, las muestras biológicas y los cartuchos utilizados deben desecharse de conformidad con las directrices de la OMS (Organización Mundial de la Salud) en cuanto a la manipulación y eliminación de desechos médicos.

Sección 14 – Información de transporte

	14.1 Número ONU	14.2 Designación oficial de transporte de la ONU	14.3 Clases de riesgo de transporte	14.4 Grupo de embalaje	14.5 Riesgos para el medioambiente
DOT	No regulado	No regulado	No regulado	No regulado	No corresponde
TDG	No regulado	No regulado	No regulado	No regulado	No corresponde
IMO/IMDG	No regulado	No regulado	No regulado	No regulado	No corresponde
IATA/ICAO	No regulado	No regulado	No regulado	No regulado	No corresponde

14.6 Precauciones especiales para el usuario

Ninguno especificado.

14.7 Transporte a granel de acuerdo con el Anexo II del MARPOL 73/78 y el código IBC

Faltan datos.

Sección 15 – Información reglamentaria

15.1 Legislación/reglamentos de seguridad, salud y medio ambiente específicos para la sustancia o mezcla

Clasificaciones de riesgo de la ley SARA Agudo

Inventario						
Componente	**CAS**	**DSL de Canadá**	**NDSL de Canadá**	**EINECS de la UE**	**ELNICS de la UE**	**TSCA**
Tiocianato de guanidinio	593-84-0	Sí	No	Sí	No	Sí

Canadá

Mano de obra

Canadá - WHMIS - Clasificación de sustancias

•Tiocianato de guanidinio	593-84-0	No listado

Canadá - WHMIS - Lista de divulgación de ingredientes

•Tiocianato de guanidinio	593-84-0	No listado

Medio ambiente

Canadá - CEPA - Lista de sustancias prioritarias

•Tiocianato de guanidinio	593-84-0	No listado

Estados Unidos

Mano de obra

EE. UU. - OSHA - Administración de seguridad de procesos - Productos químicos muy peligrosos

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - OSHA - Productos químicos regulados de manera específica

•Tiocianato de guanidinio	593-84-0	No listado

Medio ambiente

EE. UU. - CAA (Clean Air Act) - 1990 Contaminantes peligrosos del aire

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sustancias peligrosas y sus cantidades declarables

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - CERCLA/SARA - Radionucleidos y sus cantidades declarables

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades declarables de sustancias extremadamente peligrosas según la EPCRA

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades para la planificación de umbrales de sustancias extremadamente peligrosas

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 313 - Informes de emisión

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 313 - Lista de productos químicos PBT

•Tiocianato de guanidinio	593-84-0	No listado

Estados Unidos - California

Medio ambiente

EE. UU. - California - Proposición 65 - Lista de productos cancerígenos

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - California - Proposición 65 - Toxicidad en el desarrollo

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - California - Proposición 65 - Niveles máximos de dosis permitidos (MADL)

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - California - Proposición 65 - Sin niveles de riesgo significativos (NSRL)

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Mujeres

•Tiocianato de guanidinio	593-84-0	No listado

EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Hombres

• Tiocianato de guanidinio	593-84-0	No listado

15.2 Evaluación de seguridad del producto químico

No se ha llevado a cabo ninguna evaluación de seguridad química.

Sección 16 – Información adicional

Frases pertinentes (código y texto completo)	H302 - Nocivo en caso de ingestión H313 - Puede ser nocivo en contacto con la piel H320 - Provoca irritación ocular
Declaración/descargo de responsabilidad	La información anterior está basada en los datos que tenemos y la consideramos correcta. Debido a que la información puede aplicarse bajo condiciones externas a nuestro control y con las que podemos no estar familiarizados, no asumimos ninguna responsabilidad por los resultados de su uso, y todas las personas que la reciban deberán determinar por sí mismas los efectos, propiedades, protecciones y eliminación correspondientes a sus condiciones particulares. No se efectúa ninguna representación ni garantía, expresa o implícita (incluida ninguna garantía de adecuación o comerciabilidad para un objetivo concreto) respecto a los materiales, la precisión de esta información, los resultados obtenidos de su uso ni los riesgos relacionados con dicho uso del material. Tenga precaución al manipular y utilizar el material. La información superior se considera precisa y se ofrece de buena fe. Proporcionamos toda la información relacionada con la manipulación prevista del material en la fecha de publicación. Sin embargo, en caso de ocurrir un incidente adverso asociado a este producto, esta ficha de datos de seguridad no es ni debe utilizarse como sustituto de la consulta con personal formado adecuadamente.

Ficha de dados de segurança
Data de entrada em vigor: Maio de 2020
Data de substituição: Abril 2020

Xpert CT Assay
Xpert CT/NG Assay

Secção 1: Identificação da substância/mistura e da empresa/projeto

1.1 Identificador do produto

Nome do Produto **Xpert CT Assay; Xpert CT/NG Assay**
Código do produto GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Usos relevantes da substância ou mistura identificados, e usos não recomendados

Uso(s) relevante(s) identificado(s) Utilização laboratorial

1.3 Detalhes do fornecedor da ficha de dados de segurança do material

Fabricante Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Estados Unidos da América
www.cepheid.com
EUA: techsupport@cepheid.com
Telefone (Geral) 1 (888) 838-3222 - Opção 2 (EUA)
Telefone (Geral) 1 (408) 541-4191 - Fora dos EUA

Fornecedor Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Suécia
www.cepheidinternational.com
UE: support@cepheideurope.com
Telefone (Geral) 33 563 825 319 - UE

1.4 Número de telefone de emergência

Fabricante 1 (800) 535-5053 - INFOTRAC - Emergência durante 24 h
Fabricante 1 (352) 323-3500 - Fora dos EUA

Secção 2: Identificação dos Perigos

UE/CEE

Segundo: Regulamentação (CE) N.º 1272/2008 (CLP)/REACH 1907/2006 [alterada pela 453/2010]

2.1 Classificação da substância ou mistura

CLP A seguinte FDS destina-se apenas à mistura do produto final acabado usado em laboratório. O produto contém esferas e reagentes no cartucho ou nos recipientes à parte. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR.
Não classificado

2.2 Elementos do rótulo

CLP

Declarações de risco	H303 – Nocivo por ingestão H313 – Pode ser nocivo em contacto com a pele H320 – Provoca irritação ocular
Declarações de precaução	
Prevenção	P264 – Lavar cuidadosamente após manuseamento. P270 – Não comer, beber ou fumar durante a utilização deste produto.
Resposta	P301+P312 – EM CASO DE INGESTÃO: caso sinta indisposição, contacte imediatamente um CENTRO DE INFORMAÇÃO ANTIVENENOS ou um médico. P330 – Enxaguar a boca.
Armazenamento/Eliminação	P501 – Eliminar o conteúdo e/ou recipiente em conformidade com a regulamentação local, regional, nacional e/ou internacional.

2.3 Outros riscos

CLP	Este material não é considerado perigoso conforme Regulamentação (CE) N.º 1272/2008 (CLP).

GHS da ONU Revisão 3 (Rotulagem utilizada em produtos)

Segundo: Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS) da ONU: Terceira edição revista

2.1 Classificação da substância ou mistura

GHS da ONU	Toxicidade oral aguda 5 Irritação cutânea ligeira 5 Irritação ocular ligeira 2B

2.2 Elementos do rótulo

GHS da ONU

AVISO

Declarações de risco	Nocivo por ingestão Pode ser nocivo em contacto com a pele Provoca irritação ocular
Declarações de precaução	
Prevenção	Lavar cuidadosamente após manuseamento.
Resposta	Em caso de irritação cutânea: consulte um médico. SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar. Caso a irritação ocular persista: consulte um médico. Caso sinta indisposição, contacte um CENTRO DE INFORMAÇÃO ANTIVENENOS ou um médico.
Armazenamento/Eliminação	Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

2.3 Outros perigos

GHS da ONU Este produto é considerado perigoso de acordo com o Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS).

Estados Unidos da América (EUA)
Segundo: OSHA 29 CFR 1910.1200 HCS

2.1 Classificação da substância ou mistura

OSHA HCS 2012 Irritação ocular ligeira 2B

2.2 Elementos do rótulo

OSHA HCS 2012

Declarações de risco Causa irritação ocular

Declarações de precaução

Prevenção Lavar cuidadosamente após manuseamento.

Resposta SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar.
Caso a irritação ocular persista: consulte um médico.

Armazenamento/Eliminação Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

2.3 Outros perigos

OSHA HCS 2012 Este produto não é considerado perigoso ao abrigo da Regulamentação dos Estados Unidos da América (Norma sobre Comunicação de Riscos - 29 CFR 1910.1200).

Canadá
Segundo: WHMIS

2.1 Classificação da substância ou mistura

WHMIS Não classificado

2.2 Elementos do rótulo

WHMIS Não são necessários elementos do rótulo.

2.3 Outros perigos

WHMIS No Canadá, o produto acima referido não é considerado perigoso ao abrigo do Sistema de Informação de Materiais Perigosos no Local de Trabalho (WHMIS).

2.4 Outras informações

Todos os restantes reagentes, esferas e outros constituintes da mistura estão em concentrações inferiores a 1% ou não são considerados perigosos ao abrigo das regulamentações de comunicação de perigos (29 CFR 1910.1200), das diretivas da UE para a classificação e rotulagem de substâncias ou misturas ou do Sistema Mundial Harmonizado para a classificação e rotulagem de substâncias ou misturas.

Secção 3: Composição/informações sobre os ingredientes

3.1 Substâncias

O material não cumpre os critérios de uma substância.

3.2 Misturas

Composição					
Nome do produto químico	**Identificadores**	**%**	**LD50/LC50**	**Classificações de acordo com regulamentos/diretivas**	**Comentários**
Tiocianato de guanidina	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**UE CLP:** Tox. aguda 5, H302, H313, H320 **GHS da ONU:** Tox. aguda 5 (oral); Irrit. pele 5; Irrit. ocular 2B **OSHA HCS 2012:** Tox. aguda 5 (oral); Irrit. ocular 2B	NDA

Secção 4: Medidas de primeiros socorros

4.1 Descrição das medidas de primeiros socorros

Inalação Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Mover a vítima para o ar livre. Administrar oxigénio se a respiração estiver difícil. Não usar o método boca-a-boca se a vítima tiver inalado a substância; ministre respiração artificial com o auxílio de uma máscara de bolso equipada com uma válvula de 1 via ou outro dispositivo médico de respiração adequado. Administrar respiração artificial se a vítima não estiver a respirar.

Pele Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Para um pequeno contacto com a pele, evitar espalhar o material pela pele não afetada. Em caso de contacto com a substância, lavar imediatamente a pele com água corrente por pelo menos 20 minutos. Despir e isolar a roupa contaminada.

Olhos Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de contacto com a substância, lavar imediatamente os olhos com água corrente por pelo menos 20 minutos. Caso a irritação ocular persista: consulte um médico.

Ingestão Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de ingestão, lavar a boca com água (apenas se a pessoa estiver consciente). NÃO provocar o vómito. Não usar o método boca-a-boca se a vítima tiver ingerido a substância. Em caso de ingestão, consultar um médico imediatamente.

4.2 Sintomas e efeitos mais importantes, tanto agudos quanto retardados

Consultar a Secção 11 — Informação Toxicológica.

4.3 Indicação de qualquer cuidado médico imediato e tratamento especial necessários

Notas para o Médico Todos os tratamentos devem basear-se nos sinais e sintomas de perturbações observados no paciente. Deve ser considerada a possibilidade de sobrexposição a outros materiais além deste produto.

Secção 5: Medidas de combate a incêndios

5.1 Meios de extinção

Meios de extinção adequados	GRANDES INCÊNDIOS: Produto químico seco, CO2, espuma resistente ao álcool ou água pulverizada. PEQUENOS INCÊNDIOS: Produto químico seco, CO2 ou água pulverizada.
Meios de extinção inadequados	Sem dados disponíveis

5.2 Perigos especiais provocados pela substância ou mistura

Perigos de Incêndios e Explosões Incomuns	Cartucho de plástico contendo reagentes que podem emitir vapores tóxicos de óxidos de carbono, óxidos de enxofre e óxidos de azoto.
Produtos de combustão perigosos	Sem dados disponíveis

5.3 Conselhos para bombeiros

Roupas protetoras estruturais de bombeiros fornecem APENAS proteção limitada em caso de incêndio; não são eficientes em situações de derramamentos, onde é possível o contacto direto com a substância.
Usar roupa protetora contra produtos químicos que seja especificamente recomendada pelo fabricante. Poderá fornecer proteção térmica mínima ou nenhuma proteção.
Usar aparelho de respiração autónomo de pressão positiva (SCBA).
PEQUENOS INCÊNDIOS: Se não houver perigos, mover os recipientes da área de incêndio.

Secção 6: Medidas contra Libertação Acidental

6.1 Precauções individuais, equipamento protetor e procedimentos em emergências

Precauções pessoais	No caso de um cartucho se partir, aplicam-se estas precauções de proteção individual. Usar vestuário de proteção adequado. Não andar sobre material derramado. Não tocar em recipientes danificados ou material derramado a não ser que tenha vestuário de proteção adequado. Ventilar áreas fechadas.
Procedimentos de emergência	Não se prevê a necessidade de procedimentos de emergência se o material for usado em condições normais e de acordo com as recomendações.

6.2 Precauções ambientais

Evitar a entrada em cursos de água, esgotos, caves ou áreas confinadas.

6.3 Métodos e material para contenção e limpeza

Medidas de Contenção/Limpeza	Em caso de derrames pequenos, usar luvas e absorver o derrame com papel absorvente. Não eliminar os materiais derramados através da canalização.

6.4 Referências para outras secções

Consultar a Secção 8 — Controlo da Exposição/Proteção Individual e a Secção 13 — Considerações relativas à eliminação.

Secção 7: Manuseamento e armazenamento

7.1 Precauções para o manuseamento seguro

Manuseio Não necessita de manuseamento especial. Se o cartucho se partir, evitar o contacto com os reagentes derramados.

7.2 Condições para armazenamento seguro, incluindo quaisquer incompatibilidades

Armazenamento Armazenar de acordo com a documentação do produto. Manter afastado de materiais incompatíveis. Armazenar em local fechado à chave. Guardar o recipiente/embalagem bem fechado em local fresco e bem ventilado.

7.3 Utilização(ões) Final(is) Específica(s)

Consultar a Secção 1.2 — Utilizações identificadas relevantes.

Secção 8: Controlos e exposição/proteção individual

8.1 Parâmetros de controlo

	Limites de Exposição/Orientações			
	Resultado	**ACGIH**	**NIOSH**	**OSHA**
Tiocianato de guanidínio	TWA	Não estabelecidos	Não estabelecidos	Não estabelecidos

8.2 Controlos de exposição

Medidas/Controlos de Engenharia Deve usar-se uma boa ventilação geral. Os níveis de ventilação devem estar adequados às condições. Se aplicável, usar confinamento de processos, ventilação por exaustão local ou outro controlo técnico para manter os níveis de partículas disseminadas por via aérea em suspensão abaixo dos limites de exposição recomendados. Caso não tenham sido definidos limites, manter os níveis destas partículas em suspensão num nível aceitável.

Equipamento de Proteção Individual

Respiratório Não deve ser necessário equipamento respiratório se o material for utilizado nas condições normais e conforme recomendado. Caso contrário, siga as regulamentações do aparelho de respiração OSHA que se encontram na norma 29 CFR 1910.134 ou na Norma Europeia EN 149. Em caso de ultrapassagem dos limites de exposição ou da ocorrência de sintomas, usar um aparelho de respiração aprovado pelo NIOSH/MSHA ou pela Norma Europeia EN 149.

Olhos/Face Usar óculos de proteção contra salpicos de produtos químicos.

Pele/Corpo Usar vestuário de proteção

Controlos Ambientais de Exposição Seguir as melhores práticas para gestão do local e eliminação dos resíduos.

Chave para abreviaturas
OSHA = Agência para a Segurança e Saúde no Trabalho
TWA = A Média Ponderada tem por base a exposição 8 h/dia, 40 h/semana

Secção 9: Propriedades físicas e químicas

9.1 Informações sobre Propriedades Físicas e Químicas

Descrição do material			
Forma física	Líquido	Aspeto/Descrição	Os reagentes são líquidos transparentes e incolores, inodoros, que são, principalmente, tamponados em soluções aquosas.
Cor	Incolor	Odor	Inodoro
Limiar do Odor	Dados em falta		
Propriedades gerais			
Ponto de ebulição	100 °C (212 °F)	Ponto de fusão/Ponto de congelamento	0 °C (32 °F)
Temperatura de decomposição	Dados em falta	pH	3,5 a 8,8
Gravidade específica/Densidade relativa	Dados em falta	Solubilidade em água	Dados em falta
Viscosidade	Dados em falta	Propriedades explosivas	Dados em falta
Propriedades Oxidantes:	Dados em falta		
Volatilidade			
Pressão do vapor	Dados em falta	Densidade do vapor	Dados em falta
Taxa de evaporação	Dados em falta		
Inflamabilidade			
	182,2222 a 293,3333 °C (360 a 560 °F) (Reagente de ligação)	UEL	Dados em falta
LEL	Dados em falta	Autoignição	Dados em falta
Inflamabilidade (sólido/gasoso)	Dados em falta		
Ambiental			
Coeficiente de partição octanol/água	Dados em falta		

9.2 Outras Informações

Não foram observados parâmetros físico-químicos adicionais.

Secção 10: Estabilidade e reatividade

10.1 Reatividade

Desconhecida reação perigosa em condições normais de utilização.

10.2 Estabilidade química

Estável

10.3 Possibilidade de reações perigosas

Não haverá polimerização perigosa.

10.4 Condições a evitar

Materiais incompatíveis. A queima do cartucho de plástico contendo reagentes pode libertar derivados tóxicos.

10.5 Materiais incompatíveis

Ácidos, agentes oxidantes.

10.6 Produtos de decomposição perigosos

A queima do cartucho de plástico contendo reagentes pode libertar derivados tóxicos.

Secção 11: Informações toxicológicas

11.1 Informações sobre efeitos toxicológicos

Componentes		
Tiocianato de guanidínio	593-84-0	**Toxicidade aguda:** Intraperitoneal-Ratinho LD50 593 mg/kg

Propriedades do GHS	Classificação
Toxicidade aguda	**EU/CLP**•Dados em falta **GHS da ONU 3**•Toxicidade aguda - Oral 5 - ATEmix (oral) = 2965 mg/kg **OSHA HCS 2012**•Dados em falta
Corrosão/irritação cutânea	**EU/CLP**•Dados em falta **GHS da ONU 3**•Irritação cutânea ligeira 3 **OSHA HCS 2012**•Dados em falta
Lesão/irritação ocular grave	**EU/CLP**•Dados em falta **GHS da ONU 3**•Irritação ocular ligeira 2B **OSHA HCS 2012**•Irritação ocular ligeira 2B
Sensibilização da pele	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Sensibilização respiratória	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Perigo de aspiração	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Carcinogenicidade	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Mutagenicidade de células germinativas	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Toxicidade da reprodução	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-SE	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-RE	**EU/CLP**•Dados em falta **UN GHS 3**•Dados em falta **OSHA HCS 2012**•Dados em falta

Potenciais efeitos na saúde

Inalação
Agudo (Imediato) Pode provocar irritação.
Crónico (Retardado) Sem dados disponíveis
Pele
Agudo (Imediato) Provoca irritação cutânea.
Crónico (Retardado) Sem dados disponíveis
Olhos
Agudo (Imediato) Causa irritação ocular.
Crónico (Retardado) Sem dados disponíveis
Ingestão
Agudo (Imediato) Nocivo por ingestão.
Crónico (Retardado) Sem dados disponíveis

Chave para abreviaturas
LD = Dose Letal

Secção 12: Informações ecológicas

12.1 Toxicidade

LC50 (guppy): 89,1 mg/l @ 96 h

12.2 Persistência e degradabilidade

Dados dos materiais em falta.

12.3 Potencial bioacumulativo

Dados dos materiais em falta.

12.4 Mobilidade no solo

Dados dos materiais em falta.

12.5 Resultados de avaliação PBT e vPvB

Não foi feita a avaliação PB e vPvB.

12.6 Outros efeitos adversos

Não foram encontrados estudos.

Secção 13: Considerações sobre a eliminação

13.1 Métodos de tratamento de dejetos

Produto residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

Embalagem residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

13.2 Outras informações

Amostras biológicas, dispositivos de transferência e cartuchos usados devem ser considerados como tendo potencial de transmissão de agentes infecciosos que exigem precauções padrão. Siga os procedimentos relativos a resíduos ambientais da sua instituição relativamente à eliminação correta de cartuchos usados e reagentes não usados. Estes materiais podem apresentar características de resíduos químicos perigosos que exigem procedimentos de eliminação nacionais ou regionais específicos. Se as regulamentações nacionais ou regionais não disponibilizarem uma indicação clara sobre a eliminação correta, as amostras biológicas e os cartuchos usados devem ser eliminados de acordo com as diretrizes relativas ao manuseamento e à eliminação de resíduos médicos da OMS (Organização Mundial da Saúde).

Secção 14: Informações sobre transporte

	14.1 Número na ONU	14.2 Nome de transporte adequado (ONU)	14.3 Classe(s) de transporte de risco	14.4 Grupo de embalagem	14.5 Perigos ambientais
DOT	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável
TDG	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável
IMO/IMDG	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável
IATA/ICAO	Não regulamentado	Não regulamentado	Não regulamentado	Não regulamentado	Não aplicável

14.6 Precauções especiais para o utilizador

Nenhuma especificada.

14.7 Transporte a granel segundo o Anexo II de MARPOL 73/78 e o código do IBC

Dados em falta.

Secção 15: Informações regulamentares

15.1 Regulamentos/legislação de segurança, saúde e ambientais, específicos da substância ou mistura

Classificações de Risco SARA Agudo

Inventário						
Componente	**CAS**	**DSL (Canadá)**	**NDSL (Canadá)**	**EINECS (UE)**	**ELNICS (UE)**	**TSCA**
Tiocianato de guanidínio	593-84-0	Sim	Não	Sim	Não	Sim

Canadá

Trabalho

Canadá - WHMIS - Classificação de Substâncias

•Tiocianato de guanidínio	593-84-0	Não listado

Canadá - WHMIS - Lista de Divulgação de Ingredientes

•Tiocianato de guanidínio	593-84-0	Não listado

Ambiente

Canadá - CEPA - Lista de Substâncias Prioritárias

•Tiocianato de guanidínio	593-84-0	Não listado

Estados Unidos da América

Trabalho

E.U.A. - OSHA - Gestão de Segurança do Processo - Produtos Químicos Altamente Perigosos

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - OSHA - Químicos com Regulamentação Específica

•Tiocianato de guanidínio	593-84-0	Não listado

Ambiente

E.U.A. - CAA (Lei do Ar Puro) - 1990 Poluentes Atmosféricos Perigosos

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - CERCLA/SARA - Substâncias Perigosas e Respetivas Quantidades de Comunicação Obrigatória

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - CERCLA/SARA - Radionuclídeos e Respetivas Quantidades de Comunicação Obrigatória

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - CERCLA/SARA - Secção 302 Quantidades de Comunicação Obrigatória de Substâncias Extremamente Perigosas da EPCRA

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - CERCLA/SARA - Secção 302 Planeamento de Quantidades Limite de Substâncias Extremamente Perigosas

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - CERCLA/SARA - Secção 313 - Relatório de Emissão

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - CERCLA/SARA - Secção 313 - Listagem de Produtos Químicos PBT

•Tiocianato de guanidínio	593-84-0	Não listado

Estados Unidos da América - Califórnia

Ambiente

E.U.A. - Califórnia - Proposta 65 - Lista de Substâncias Cancerígenas

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - Califórnia - Proposta 65 - Toxicidade para o Desenvolvimento

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - Califórnia - Proposta 65 - Níveis Máximos de Dose Permitidos (MADL)

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - Califórnia - Proposta 65 - Sem Níveis de Risco Significativos (NSRL)

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Mulheres

•Tiocianato de guanidínio	593-84-0	Não listado

E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Homens

•Tiocianato de guanidínio	593-84-0	Não listado

15.2 Avaliação da Segurança Química

Não foi efetuada qualquer Avaliação da Segurança Química.

Secção 16: Outras informações

Frases relevantes (código e texto completo)	H302 – Nocivo por ingestão H313 – Pode ser nocivo em contacto com a pele H320 – Provoca irritação ocular
Renúncia/ Declaração de responsabilidade	A informação supramencionada baseia-se em dados que nos foram disponibilizados e é tida como correta. Dado que a informação pode ser aplicada em condições fora do nosso controlo e com as quais podemos não estar familiarizados, não assumimos qualquer responsabilidade pelo resultado da sua utilização, e todas as pessoas que a recebam têm de determinar individualmente os efeitos, as propriedades, as proteções e os procedimentos de eliminação que se aplicam às suas condições particulares. Não se assume qualquer representação ou garantia, implícita ou explicitamente (incluindo garantia de adequação ou comerciabilidade para uma finalidade específica) em relação aos materiais, à exatidão desta informação, aos resultados obtidos decorrentes da sua utilização ou a perigos relacionados com a utilização deste material. Deve-se ter cuidado no manuseamento e utilização deste material. A informação anterior é disponibilizada de boa-fé e é tida como exata. À data de emissão, fornecemos toda a informação relevante para um manuseamento previsível do material. No entanto, caso ocorra um incidente adverso associado a este produto, esta ficha de dados de segurança não substitui, nem se pretende que substitua, a consulta de um profissional com formação adequada.

Chave para abreviaturas
NDA = Nenhuns Dados Disponíveis

Паспорт безопасности материала
Дата вступления в силу: Май 2020 г.
Отменяет версию документа за: Апрель 2020 г.

Xpert CT Assay
Xpert CT/NG Assay

Раздел 1. Общие сведения о веществе/смеси и производителе

1.1 Идентификатор продукта

Наименование продукта **Xpert CT Assay; Xpert CT/NG Assay**

Код продукта GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Рекомендованные и не рекомендованные способы применения вещества или смеси

Рекомендованные способы применения Для использования в лабораторных условиях

1.3 Сведения об организации, предоставившей паспорт безопасности материала

Производитель Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
EUA: techsupport@cepheid.com

Телефон (общий) 1 (888) 838-3222 – США, дополнит. 2

Телефон (общий) 1 (408) 541-4191 – За пределами США

Поставщик Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
UE: support@cepheideurope.com

Телефон (общий) 33 563 825 319 – ЕС

1.4 Телефон для экстренной связи

Производитель 1 (800) 535-5053 – INFOTRAC – круглосуточный телефон экстренного вызова

Производитель 1 (352) 323-3500 – За пределами США

Раздел 2. Идентификация опасности

ЕС/ЕЭС

Согласно: Регламенту ЕК (ЕС) № 1272/2008 (CLP)/REACH 1907/2006 [с поправками, внесенными постановлением 453/2010]

2.1 Классификация вещества или смеси

Регламент CLP Следующий паспорт безопасности материала действителен только для готовой смеси, используемой в лабораторных условиях. Продукт содержит гранулы и реактивы в картридже или в отдельных контейнерах. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1)&(2).
Не классифицируется

2.2 Элементы маркировки

Регламент CLP

Указания на опасность	H302 – Вредно при проглатывании H313 – Может причинить вред при попадании на кожу H320 – Вызывает раздражение глаз
Меры предосторожности	
Профилактика	P264 – После использования тщательно вымыть. P270 – Не принимать пищу, не пить и не курить в процессе использования этого продукта.
Реагирование	P301+P312 – ДЕЙСТВИЯ ПРИ ПРОГЛАТЫВАНИИ. При плохом самочувствии немедленно обратиться в ТОКСИКОЛОГИЧЕСКИЙ ЦЕНТР или к врачу-специалисту/терапевту. P330 – Прополоскать рот.
Хранение/удаление в отходы	P501 – Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

2.3 Другие факторы опасности

Регламент CLP	Согласно Регламенту ЕК № 1272/2008 (CLP) этот материал не считается опасным.

СГС ООН, редакция 3 (Содержание маркировки, указываемой на продукции)

Согласно: Согласованная на глобальном уровне система классификации опасности и маркировки химической продукции (СГС) ООН: третья пересмотренная редакция

2.1 Классификация вещества или смеси

СГС ООН	Острая токсичность, перорально, 5 Слабое раздражение кожи, 5 Слабое раздражение глаз, 2B

2.2 Элементы маркировки

СГС ООН

ВНИМАНИЕ!

Указания на опасность	Вредно при проглатывании Может причинить вред при попадании на кожу Вызывает раздражение глаз
Меры предосторожности	
Профилактика	После использования тщательно вымыть.
Реагирование	При раздражении кожи: обратиться за медицинской консультацией/помощью. ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью. При плохом самочувствии обратиться в ТОКСИКОЛОГИЧЕСКИЙ ЦЕНТР или к врачу-специалисту/терапевту.

Хранение/удаление в отходы	Удаление в отходы содержимого и/или тары должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

2.3 Другие факторы опасности

СГС ООН	В соответствии с Согласованной на глобальном уровне системой классификации опасности и маркировки химической продукции (СГС) данный продукт считается опасным.

США
Согласно: OSHA 29 CFR 1910.1200 HCS

2.1 Классификация вещества или смеси

OSHA HCS 2012	Слабое раздражение глаз, 2B

2.2 Элементы маркировки

OSHA HCS 2012

Указания на опасность	Вызывает раздражение глаз.
Меры предосторожности	
Профилактика	После использования тщательно вымыть.
Реагирование	ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.
Хранение/удаление в отходы	Удаление в отходы содержимого и/или тары должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

2.3 Другие факторы опасности

OSHA HCS 2012	Согласно государственным нормам США (документ 29 CFR 1910.1200 – Стандарт-требование об оповещении об опасности) этот продукт не считается опасным.

Канада
Согласно: WHMIS

2.1 Классификация вещества или смеси

WHMIS	Не классифицируется

2.2 Элементы маркировки

WHMIS	Маркировка не требуется.

2.3 Другие факторы опасности

WHMIS	В Канаде указанное выше вещество согласно требованиям Информационной системы по опасным материалам на рабочих местах (WHMIS) не считается опасным.

2.4 Дополнительная информация

Все остальные реактивы, гранулы и прочие составляющие представлены в смеси в концентрациях менее 1% или не считаются опасными согласно Стандартам-требованиям США об оповещении об опасности (29 CFR 1910.1200), директивам ЕС в отношении классификации и маркировки веществ и смесей и Согласованной на глобальном уровне системе классификации опасности и маркировки химической продукции (СГС).

Раздел 3. Состав/информация о компонентах

3.1 Вещества

Материал не отвечает критериям классификации, применяемым к веществам.

3.2 Смеси

Состав					
Химическое наименование	**Идентификаторы**	**%**	**LD50/LC50**	**Классификация в соответствии с нормами/постановлениями**	**Комментарии**
Гуанидина тиоцианат	**CAS:** 593-84-0 **EINECS:** 209-812-1	10–20%	593 мг/кг	**EU CLP:** острая токсичность 5, H302, H313, H320 **СГС ООН:** острая токсичность 5 (перорально); раздражение кожи 5; раздражение глаз 2B **OSHA HCS 2012:** острая токсичность 5 (перорально); раздражение глаз 2B	Нет данных

Раздел 4. Первая медицинская помощь

4.1 Описание мер первой медицинской помощи

Вдыхание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. Вынести пострадавшего на свежий воздух. При затрудненном дыхании дать кислород. При вдыхании вещества не применять искусственное дыхание рот-в-рот. Выполнить искусственное дыхание с помощью карманной маски с клапаном одностороннего действия или другого подходящего медицинского устройства. При остановке дыхания обеспечить искусственное дыхание/ИВЛ.

Кожа Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При незначительном контакте с кожей избегайте распространения материала на незатронутые участки. В случае контакта вещества с кожей незамедлительно промыть пораженный участок проточной водой в течение не менее чем 20 минут. Снять и изолировать загрязненную одежду.

Глаза Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. В случае попадания вещества незамедлительно промыть глаза проточной водой в течение не менее чем 20 минут. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

Проглатывание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При проглатывании прополоскать рот водой (только если человек находится в сознании). НЕ вызывать рвоту. Не применять искусственное дыхание рот-в-рот при проглатывании вещества. При проглатывании материала сразу же обратиться к врачу.

4.2 Наиболее важные симптомы и последствия, проявляющиеся немедленно и с задержкой

См. раздел 11, «Токсикологическая информация».

4.3 Признаки необходимости неотложной медицинской помощи и специального лечения

Примечания для врача Лечение основывать на наблюдаемых симптомах. Учитывать возможность одновременного чрезмерного воздействия на пациента и других веществ, помимо данного продукта.

Раздел 5. Меры противопожарной безопасности

5.1 Средства пожаротушения

Подходящие средства пожаротушения КРУПНЫЕ ПОЖАРЫ. Сухое химическое огнетушащее средство, углекислый газ (CO2), спиртоустойчивые пенообразователи, распыленная вода.
НЕБОЛЬШИЕ ПОЖАРЫ. Сухое химическое огнетушащее средство, углекислый газ (CO2), распыленная вода.

Непригодные средства пожаротушения Данные отсутствуют

5.2 Особые аспекты опасности вещества или смеси

Особая огне- и взрывоопасность Пластмассовый картридж содержит реактивы, способные выделять токсичные испарения: оксиды углерода, оксиды серы, оксиды азота.

Опасные продукты горения Данные отсутствуют

5.3 Рекомендации по пожаротушению

Защитная одежда пожарных для тушения пожаров в зданиях обеспечивает ограниченную защиту ТОЛЬКО в условиях пожара; она не является эффективным средством защиты при разливах с возможным непосредственным контактом с веществами.
Носить одежду для химической защиты, рекомендованную производителем. Она может быть малоэффективна или неэффективна в качестве тепловой защиты.
Использовать автономные дыхательные аппараты, работающие в режиме положительного давления.
НЕБОЛЬШИЕ ПОЖАРЫ. Уберите контейнеры из зоны пожара, если можете сделать это без риска.

Раздел 6. Меры по предотвращению и ликвидации последствий случайного выброса материала

6.1 Меры по обеспечению личной безопасности, средства защиты и действия в чрезвычайной ситуации

Меры по обеспечению личной безопасности В случае разбития картриджа актуальны указанные меры по обеспечению личной безопасности. Используйте соответствующую защитную одежду. Не ходите по разлитому/просыпанному материалу. Не прикасайтесь к поврежденным контейнерам или разлитому/просыпанному материалу, если нет соответствующей защитной одежды. Проветрите закрытые помещения.

Действия в чрезвычайных ситуациях Ожидается, что экстренные меры не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций.

6.2 Меры по защите окружающей среды

Не допускать попадания в водотоки, канализацию, подвалы и замкнутые пространства.

6.3 Методы и средства локализации и очистки

Методы и средства локализации и очистки — При небольших разливах используйте перчатки. Для сбора вещества используйте бумажные полотенца. Не сливать пролитые вещества в канализацию.

6.4 Ссылки на другие разделы

См. раздел 8, «Меры контроля воздействия и средства индивидуальной защиты», и раздел 13, «Условия удаления в отходы».

Раздел 7. Правила обращения и хранения

7.1 Меры предосторожности при обращении с продуктом

Обращение — Особое обращение не требуется. В случае разбития картриджа избегайте контакта с разлившимися реактивами.

7.2 Условия безопасного хранения и учет факторов несовместимости

Место хранения — Хранить согласно указаниям на упаковке. Хранить вдали от несовместимых материалов. Хранить под замком. Хранить в плотно закрытом контейнере/упаковке в прохладном, хорошо проветриваемом месте.

7.3 Особые способы применения

См. раздел 1.2, «Рекомендованные способы применения».

Раздел 8. Меры контроля воздействия и средства индивидуальной защиты

8.1 Контрольные параметры

	Предельно допустимые концентрации/рекомендации			
	Результат	**ACGIH**	**NIOSH**	**OSHA**
Гуанидинтиоцианат	TWA	Не установлено	Не установлено	Не установлено

8.2 Меры контроля воздействия

Инженерно-технические мероприятия/средства контроля — Следует обеспечить хорошую общую вентиляцию. Интенсивность вентиляции должна соответствовать условиям хранения/использования. Если возможно, используйте изолированное рабочие пространство, местную вытяжную вентиляцию и прочие инженерно-технические средства для сдерживания концентрации вещества в воздухе на уровне ниже ПДК. Если ПДК не установлены, поддерживайте приемлемые концентрации вещества в воздухе.

Индивидуальные средства защиты

Защита органов дыхания — Ожидается, что средства защиты органов дыхания не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций. В противном случае соблюдайте рекомендации по использованию респираторов Управления охраны труда (OSHA) США, изложенные в документе 29 CFR 1910.134, или Европейского стандарта EN 149. При превышении ПДК или обнаружении признаков поражения используйте респираторы, одобренные Национальным институтом по безопасности и гигиене труда (NIOSH) США, Управлением по безопасности и охране труда в добывающей промышленности (MSHA) США или Европейским стандартом EN 149.

Защита глаз/лица	Носите очки химической защиты.
Защита кожных покровов/тела	Используйте защитную одежду.
Защита окружающей среды	Соблюдайте общие правила работы на объекте и удаления отходов.

Сокращения
OSHA = Управление охраны труда, США (Occupational Safety and Health Administration).
TWA = Средневзвешенная во времени концентрация, вычисляемая на основании воздействия в течение 8 часов в день, 40 часов в неделю.

Раздел 9. Физические и химические свойства

9.1 Информация о физических и химических свойствах

Описание материала			
Физическая форма	Жидкость	Внешний вид/описание	Реактивы представляют собой прозрачные бесцветные жидкости без запаха, в основном буферизованные в водных растворах.
Цвет	Прозрачная	Запах	Без запаха
Порог ощущения запаха	Данные отсутствуют		
Общие свойства			
Точка кипения	100 °C (212 °F)	Температура плавления/замерзания	0 °C (32 °F)
Температура разложения	Данные отсутствуют	pH	от 3,5 до 8,8
Удельный вес/относительная плотность	Данные отсутствуют	Растворимость в воде	Данные отсутствуют
Вязкость	Данные отсутствуют	Взрывчатые свойства	Данные отсутствуют
Окислительные свойства:	Данные отсутствуют		
Летучесть			
Давление паров	Данные отсутствуют	Плотность паров	Данные отсутствуют
Интенсивность испарения	Данные отсутствуют		
Воспламеняемость			
	от 182,2222 до 293,3333 °C (от 360 до 560 °F) (реактив связывания)	ВКПВ (верхний предел взрываемости)	Данные отсутствуют
НПВ (нижний предел взрываемости)	Данные отсутствуют	Самовоспламенение	Данные отсутствуют
Воспламеняемость (в твердом, газообразном состоянии)	Данные отсутствуют		
В отношении окружающей среды			
Коэффициент распределения октанол/вода	Данные отсутствуют		

9.2 Дополнительная информация

Дополнительные физические и химические свойства не обнаружены.

Раздел 10. Стабильность и реакционная способность

10.1 Реакционная способность

В нормальных условиях использования опасные реакции неизвестны.

10.2 Химическая стабильность

Стабильно

10.3 Вероятность опасных реакций

Опасная полимеризация не происходит.

10.4 Условия, которых следует избегать

Несовместимые материалы. При сжигании пластмассового картриджа, содержащего реактивы, могут высвобождаться токсические вещества.

10.5 Несовместимые материалы

Кислоты, окислители.

10.6 Опасные продукты разложения

При сжигании пластмассового картриджа, содержащего реактивы, могут высвобождаться токсические вещества.

Раздел 11. Токсикологическая информация

11.1 Информация о токсикологических последствиях

Компонент		
Гуанидинтиоцианат	593-84-0	**Острая токсичность:** внутрибрюшинное введение - мышь LD50 • 593 мг/кг

Свойства (СГС)	Классификация
Острая токсичность	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Острая токсичность – перорально – категория 5 – расчетная оценка острой токсичности ATEmix (пероральное введение) = 2965 мг/кг **OSHA HCS 2012** • Данные отсутствуют
Разъедающее/раздражающее воздействие на кожу	**EU/CLP** • Данные отсутствуют **СГС ООН 3**• Слабое раздражение кожи, категория 3 **OSHA HCS 2012** • Данные отсутствуют
Серьезное повреждение/раздражение глаз	**EU/CLP** • Данные отсутствуют **СГС ООН 3**• Слабое раздражение глаз, категория 2B **OSHA HCS 2012** • Слабое раздражение глаз, категория 2B
Сенсибилизация кожи	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Сенсибилизация органов дыхания	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Опасность при аспирации	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Канцерогенность	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Мутагенность для зародышевых клеток	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют

Свойства (СГС)	Классификация
Токсическое действие на репродуктивную функцию	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Органоспецифическая токсичность при однократном воздействии (STOT-SE)	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Органоспецифическая токсичность при многократном воздействии (STOT-RE)	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют

Возможные последствия для здоровья

Вдыхание
Острые последствия Может вызвать раздражение.
Хронические последствия Данные отсутствуют

Кожа
Острые последствия Вызывает раздражение кожи.
Хронические последствия Данные отсутствуют

Глаза
Остро выраженные последствия Вызывает раздражение глаз.
Хронические последствия Данные отсутствуют

Проглатывание
Острые последствия Вредно при проглатывании.
Хронические последствия Данные отсутствуют

Сокращения
LD = Летальная доза

Раздел 12. Информация о воздействии на окружающую среду

12.1 Токсичность

LC50 (гуппи): 89,1 мг/л за 96 ч

12.2 Устойчивость и способность к разложению

Данные о материале отсутствуют.

12.3 Способность к биоаккумуляции

Данные о материале отсутствуют.

12.4 Подвижность в почве

Данные о материале отсутствуют.

12.5 Результаты оценки соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества»

Оценка соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества» не производилась.

12.6 Другие неблагоприятные последствия

Исследования не проводились.

Раздел 13. Условия удаления в отходы

13.1 Методы переработки отходов

Отходы продукта Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

Отходы упаковки Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

13.2 Дополнительная информация

Биологические образцы, устройства для переноса и использованные картриджи следует считать возможными переносчиками возбудителей инфекционных заболеваний, и они требуют соблюдения стандартных мер предосторожности. Для правильного удаления в отходы использованных картриджей и неиспользованных реактивов выполняйте принятые в вашем учреждении правила защиты окружающей среды. Эти материалы могут иметь свойства химически опасных отходов и требовать выполнения особых национальных или региональных процедур удаления в отходы. Если принятые в стране или регионе правила не дают ясных указаний по правильному удалению в отходы, биологические образцы и использованные картриджи следует удалять в отходы с соблюдением правил ВОЗ (Всемирной организации здравоохранения) относительно обращения с медицинскими отходами и их удаления.

Раздел 14. Информация о транспортировке

	14.1 Номер ООН	14.2 Отгрузочное наименование ООН	14.3 Классы опасности при транспортировке	14.4 Группа упаковки	14.5 Опасность для окружающей среды
DOT	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо
TDG	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо
IMO/IMDG	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо
IATA/ICAO	Не регулируется	Не регулируется	Не регулируется	Не регулируется	Неприменимо

14.6 Специальные меры предосторожности для пользователей

Не указаны.

14.7 Бестарная транспортировка в соответствии с Приложением II MARPOL 73/78 и Кодексом IBC

Данные отсутствуют.

Раздел 15. Нормативная информация

15.1 Правовые акты в сфере безопасности, защиты здоровья и окружающей среды/особые правовые акты, применимые к веществу или смеси

Класс опасности (SARA) Острая

	Реестр					
Компонент	**CAS**	**Канада, DSL**	**Канада, NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Гуанидинтиоцианат	593-84-0	Да	Нет	Да	Нет	Да

Канада

Охрана труда

Канада – Информационная система по опасным материалам на рабочих местах (WHMIS) – Классификация веществ
•Гуанидинтиоцианат 593-84-0 Не числится

Канада – WHMIS – Перечень ингредиентов, информация о которых подлежит раскрытию
•Гуанидинтиоцианат 593-84-0 Не числится

Окружающая среда

Канада – Закон Канады об охране окружающей среды (CEPA) – Список приоритетных веществ
•Гуанидинтиоцианат 593-84-0 Не числится

США

Охрана труда

США – Управление охраны труда (OSHA) – Обеспечение безопасности производственного процесса – Высокоопасные химические вещества
•Гуанидинтиоцианат 593-84-0 Не числится

США – OSHA – Особо контролируемые химические вещества
•Гуанидинтиоцианат 593-84-0 Не числится

Окружающая среда

США – Закон о чистом воздухе (CAA), 1990 – Опасные загрязняющие воздух вещества
•Гуанидинтиоцианат 593-84-0 Не числится

Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон об улучшении финансирования и перераспределении полномочий (SARA) – Опасные вещества и их подотчетные количества
•Гуанидинтиоцианат 593-84-0 Не числится

США – CERCLA/SARA – Радионуклиды и их подотчетные количества
•Гуанидинтиоцианат 593-84-0 Не числится

США – CERCLA/SARA – Раздел 302 – Чрезвычайно опасные вещества. Закон о планировании действий при чрезвычайных ситуациях и праве общества на информацию (EPCRA) – подотчетные количества
•Гуанидинтиоцианат 593-84-0 Не числится

США – CERCLA/SARA – Раздел 302 – Чрезвычайно опасные вещества. Пороговые запланированные количества (TPQ)
•Гуанидинтиоцианат 593-84-0 Не числится

США – CERCLA/SARA – Раздел 313. Оповещение о выбросах
•Гуанидинтиоцианат 593-84-0 Не числится

США – CERCLA/SARA – Раздел 313. Список устойчивых биоаккумулятивных токсических веществ
•Гуанидинтиоцианат 593-84-0 Не числится

США – Калифорния

Окружающая среда

США – Калифорния – Предложение 65 – Список канцерогенов		
•Гуанидинтиоцианат	593-84-0	Не числится
США – Калифорния – Предложение 65 – Эмбрифетотоксичность		
•Гуанидинтиоцианат	593-84-0	Не числится
США – Калифорния – Предложение 65 – Предельно допустимые дозы (MADL)		
•Гуанидинтиоцианат	593-84-0	Не числится
США – Калифорния – Предложение 65 – Концентрации веществ, не несущие значимого риска (NSRL)		
•Гуанидинтиоцианат	593-84-0	Не числится
США – Калифорния – Предложение 65 – Влияние на женский организм		
•Гуанидинтиоцианат	593-84-0	Не числится
США – Калифорния – Предложение 65 – Влияние на мужской организм		
•Гуанидинтиоцианат	593-84-0	Не числится

15.2 Оценка химической безопасности

Оценка химической безопасности не проводилась.

Раздел 16. Дополнительная информация

Соответствующие фразы (код и текст)

H302 – Вредно при проглатывании
H313 – Может причинить вред при попадании на кожу
H320 – Вызывает раздражение глаз

Отказ от ответственности/ ограничение ответственности

Представленные выше сведения основаны на доступных нам данных и считаются верными. В связи с тем, что представленная информация может быть использована в независящих от нас и неизвестных нам условиях, мы не несем ответственность за последствия ее использования, а все лица, получающие эту информацию, должны самостоятельно принимать решения относительно последствий применения, свойств, средств защиты и способов удаления в отходы в соответствии с конкретными условиями применения. Мы не заявляем, не даем каких-либо гарантий и поручительств, явных или подразумеваемых (включая гарантии пригодности или товарной пригодности для конкретной цели), в отношении материалов и точности информации, полученных при их использовании результатов, а также опасностей, связанных с использованием данного материала. При обращении с материалом и его использовании следует проявлять осторожность. Представленная выше информация передана добросовестно с уверенностью в ее точности. Мы предоставляем всю информацию, касающуюся предполагаемого использования материала, по состоянию на момент публикации. Однако в случае нежелательных последствий, связанных с данным продуктом, настоящий паспорт безопасности материала не является и не может являться заменой консультации с соответствующим специалистом.

Паспорт з безпеки
Дата набрання чинності: Травень, 2020 р.
Заміняє версію документу від: Квітень 2020 р.

Xpert CT Assay
Xpert CT/NG Assay

Розділ 1: Загальні відомості про речовину/суміш та компанію/виробника

1.1 Ідентифікатор продукту

Назва продукту **Xpert CT Assay; Xpert CT/NG Assay**

Код продукту GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Рекомендовані і нерекомендовані способи використання речовини або суміші

Рекомендовані способи використання Для використання в лабораторних умовах

1.3 Інформація про організацію, що надала паспорт з безпеки продукту

Виробник Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Сполучені Штати Америки
www.cepheid.com
США: techsupport@cepheid.com

Телефон (загальний) 1 (888) 838-3222 - США варіант 2

Телефон (загальний) 1 (408) 541-4191 - За межами США

Постачальник Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Швеція
www.cepheidinternational.com
ЄС: support@cepheideurope.com

Телефон (загальний) 33 563 825 319 – ЄС

1.4 Номер екстреної служби

Виробник 1 (800) 535-5053 - INFOTRAC - цілодобовий телефон екстреного виклику

Виробник 1 (352) 323-3500 - За межами США

Розділ 2: Визначення небезпеки

ЄС/ЄЄС

Відповідно до: Регламенту (ЄС) № 1272/2008 (CLP)/REACH 1907/2006 [з поправками, внесеними постановою 453/2010]

2.1 Класифікація речовини або суміші

Регламент CLP Цей паспорт з безпеки продукту дійсний лише для готової суміші, яка використовується в лабораторних умовах. У складі продукту містяться гранули та реактиви в картриджі або в окремих контейнерах. Винятки щодо розкриття інформації щодо деяких компонентів відповідають вимогам Статті 1(5)(d) Регламенту CLP і розділу 29 Кодексу федеральних правил (CFR) США 1910.1200(g)(2)(i)(C)(1)&(2).
Не класифікується

2.2 Елементи маркування

Регламент CLP

Повідомлення про небезпеку
H302 – Шкідливо в разі ковтання
H313 – Може завдати шкоди у разі контакту зі шкірою
H320 – Викликає подразнення очей

Вказівки щодо безпеки

Профілактика
P264 – Після використання ретельно вимити.
P270 – Не їжте, не пийте та не куріть під час використання цієї продукції.

Заходи реагування
P301+312 – У РАЗІ ПРОКОВТУВАННЯ: У разі поганого самопочуття негайно звернутися в ТОКСИКОЛОГІЧНИЙ ЦЕНТР або до лікаря-фахівця чи терапевта.
P330 – Прополощіть рот.

Зберігання/утилізація
P501 – Утилізуйте вміст та (або) контейнер відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

2.3 Інші небезпеки

Регламент CLP
Згідно з Постановою (ЄС) № 1272/2008 (CLP), цей матеріал не вважається небезпечним.

Глобально узгоджена в рамках ООН система класифікації небезпеки і маркування хімічної продукції (ГУС), версія 3 (Зміст етикеток, наявних на продукції)

Відповідно до: Глобально узгодженої в рамках ООН системи класифікації небезпеки і маркування хімічної продукції (ГУС) Третя переглянута редакція

2.1 Класифікація речовини або суміші

ГУС ООН
Гостра токсичність перорально 5
Незначне подразнення шкіри 5
Незначне подразнення очей 2B

2.2 Елементи маркування

ГУС ООН

ЗАСТЕРЕЖЕННЯ

Повідомлення про небезпеку
Шкідливо в разі ковтання
Може завдати шкоди у разі контакту зі шкірою
Викликає подразнення очей

Вказівки щодо безпеки

Профілактика
Після використання ретельно промити.

Заходи реагування
У разі подразнення шкіри: Звернутися за медичною консультацією або по допомогу.
У РАЗІ ПОТРАПЛЯННЯ В ОЧІ: Обережно промийте водою протягом кількох хвилин. Зняти контактні лінзи, якщо вони є та якщо це легко зробити. Продовжити промивання.
Якщо подразнення очей не проходить: Звернутися за медичною консультацією або по допомогу.
У разі поганого самопочуття звернутися в ТОКСИКОЛОГІЧНИЙ ЦЕНТР або до лікаря-фахівця чи терапевта.

Зберігання/утилізація
Утилізацію вмісту та (або) контейнера необхідно здійснювати відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

2.3 Інші небезпеки

ГУС ООН Відповідно до Глобально узгодженої системи класифікації небезпеки і маркування хімічної продукції (ГУС), даний продукт вважається небезпечним.

Сполучені Штати (США)
Відповідно до: OSHA 29 CFR 1910.1200 HCS

2.1 Класифікація речовини або суміші

OSHA HCS 2012 Незначне подразнення очей 2B

2.2 Елементи маркування

OSHA HCS 2012

Повідомлення про небезпеку	Викликає подразнення очей
Вказівки щодо безпеки	
Профілактика	Після використання ретельно промити.
Заходи реагування	У РАЗІ ПОТРАПЛЯННЯ В ОЧІ: Обережно промийте водою протягом кількох хвилин. Зняти контактні лінзи, якщо вони є та якщо це легко зробити. Продовжити промивання. Якщо подразнення очей не проходить: Звернутися за медичною консультацією або по допомогу.
Зберігання/утилізація	Утилізацію вмісту та (або) контейнера необхідно здійснювати відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

2.3 Інші небезпеки

OSHA HCS 2012 Відповідно до державних норм США (29 CFR 1910.1200 - Стандарт інформування про небезпечні речовини), цей продукт не вважається небезпечним.

Канада
Відповідно до: WHMIS

2.1 Класифікація речовини або суміші

WHMIS Не класифікується

2.2 Елементи маркування

WHMIS Наявність елементів етикетки не обов'язкова.

2.3 Інші небезпеки

WHMIS У Канаді згаданий вище продукт не вважається небезпечним згідно з Інформаційною системою небезпечних матеріалів на робочому місці (Workplace Hazardous Materials Information System).

2.4 Додаткова інформація

Всі інші реактиви, гранули та інші складові представлені в суміші в концентраціях менше 1% або не вважаються небезпечними згідно зі Стандартами-вимогами США щодо сповіщення про небезпеку (29 CFR 1910.1200), директивами ЄС щодо класифікації та маркування речовин і сумішей і Глобальної узгодженої системи класифікації небезпеки та маркування речовин або сумішей (ГУС).

Розділ 3: Склад/Інформація про компоненти

3.1 Речовини

Матеріал не відповідає критеріям речовини.

3.2 Суміші

Склад					
Хімічне найменування	**Ідентифікатори**	**%**	**LD50/LC50**	**Класифікація відповідно до Норм/Директиви**	**Коментарі**
Гуанідинтіоціанат	**CAS:** 593-84-0 **EINECS:** 209-812-1	10%-20%	593 mg/kg (мг/кг)	**ЄС CLP:** Гостра токсичність 5, H302, H313, H320 **ГУС ООН:** Гостра токсичність 5 (перорально); Подразнення шкіри 5; Подразнення очей 2B **OSHA HCS 2012:** Гостра токсичність 5 (перорально); Подразнення очей 2B	NDA

Розділ 4: Заходи першої медичної допомоги

4.1 Опис заходів першої медичної допомоги

Вдихання

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. Винести потерпілого на свіже повітря. При утрудненому диханні дати кисень. При вдиханні речовини не застосовувати штучне дихання рот-в-рот. Виконати штучне дихання за допомогою кишенькової маски з клапаном односторонньої дії або іншого відповідного медичного пристрою. При зупинці дихання забезпечити штучне дихання.

Шкіра

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. При незначному контакті зі шкірою уникайте поширення матеріалу на непошкоджені ділянки. У разі контакту речовини зі шкірою негайно промити уражену ділянку проточною водою протягом не менше ніж 20 хвилин. Зняти та ізолювати забруднений одяг.

Очі

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. У разі потрапляння речовини негайно промити очі проточною водою протягом не менше ніж 20 хвилин. Якщо подразнення очей не проходить: Звернутися за медичною консультацією або по допомогу.

Ковтання

Перша медична допомога не передбачається, якщо матеріал використовується в звичайних умовах та у відповідності до рекомендацій. При ковтанні прополоскати рот водою (тільки якщо людина знаходиться в свідомості). НЕ викликайте блювоту. Не застосовувати штучне дихання рот-в-рот при ковтанні речовини. При ковтанні матеріалу негайно звернутися до лікаря.

4.2 Найважливіші симптоми та наслідки, гострі та ті, що проявляються з затримкою

Див. Розділ 11 - Токсикологічна інформація.

4.3 Признаки необхідної невідкладної медичної допомоги та спеціального лікування

Примітки для лікаря

Всі методи лікування повинні грунтуватися на ознаках та симптомах тривоги, що спостерігаються у пацієнта. Слід враховувати можливість одночасного надмірного впливу на пацієнта й інших речовин, окрім даного продукту.

Розділ 5: Заходи протипожежної безпеки

5.1 Засоби гасіння пожежі

Придатні засоби гасіння пожежі	ВЕЛИКІ ПОЖЕЖІ: Сухий хімічний вогнегасний засіб, вуглекислий газ (CO2), спиртостійкі піноутворювачі або водяний спрей. НЕВЕЛИКІ ПОЖЕЖІ: Сухий хімічний вогнегасний засіб, вуглекислий газ (CO2) або водяний спрей.
Непридатні засоби гасіння пожежі	Дані відсутні

5.2 Особливі аспекти небезпеки, що виникають від речовини або суміші

Незвичайна вогненебезпека та вибухонебезпека	Пластмасовий картридж містить реактиви, здатні виділяти токсичні випари: оксиди вуглецю, оксиди сірки, оксиди азоту.
Небезпечні продукти горіння	Дані відсутні

5.3 Поради для пожежників

Захисний одяг пожежників для гасіння пожеж в будівлях забезпечує обмежений захист ТІЛЬКИ в умовах пожежі; він не є ефективним засобом захисту при розливах з можливим безпосереднім контактом з речовинами.
Носити одяг для хімічного захисту, спеціально рекомендований виробником. Він може бути малоефективний або неефективний в якості теплового захисту.
Використовувати автономні дихальні апарати, що працюють в режимі позитивного тиску (Self-Contained Breathing Apparatus).
НЕВЕЛИКІ ПОЖЕЖІ: Заберіть контейнери із зони пожежі, якщо можете зробити це без ризику.

Розділ 6: Заходи щодо наслідків випадкового викиду матеріалу

6.1 Заходи щодо забезпечення особистої безпеки, засоби захисту та дії при надзвичайній ситуації

Заходи щодо забезпечення особистої безпеки	У разі розбиття картриджа актуальні зазначені заходи щодо забезпечення особистої безпеки. Використовуйте відповідний захисний одяг. Не ходіть по розлитому матеріалу. Не торкайтеся пошкоджених контейнерів або розлитого матеріалу, якщо немає відповідного захисного одягу. Провітріть закриті приміщення.
Дії при надзвичайній ситуації	Очікується, що заходи при надзвичайних ситуаціях не будуть потрібні, якщо матеріал використовується в звичайних умовах і з дотриманням рекомендацій.

6.2 Заходи по захисту навколишнього середовища

Не допускати викидання у водостоки, каналізацію, підвали і замкнутий простір.

6.3 Методи і засоби локалізації і очищення

Засоби локалізації і очищення	При невеликих розливах використовуйте рукавички. Для збору речовини використовуйте паперові рушники. Не зливати пролиті речовини в каналізацію.

6.4 Посилання на інші розділи

Див. Розділ 8, «Заходи контролю впливу та засоби індивідуального захисту», і розділ 13, «Умови утилізації».

Розділ 7: Правила поводження та зберігання

7.1 Запобіжні заходи з метою безпечного поводження з продуктом

Поводження Не потребує особливого поводження. У разі розбиття картриджа уникайте контакту з розлитими реактивами.

7.2 Умови безпечного зберігання, враховуючи всі фактори несумісності

Зберігання Зберігати відповідно до вказівок на упаковці. Тримати подалі від несумісних матеріалів. Зберігати під замком. Зберігати в щільно закритому контейнері/упаковці в прохолодному, добре провітрюваному місці.

7.3 Особливі способи застосування

Див. Розділ 1.2 - Рекомендовані і нерекомендовані способи використання речовини або суміші.

Розділ 8: Заходи контролю впливу та засоби індивідуального захисту

8.1 Параметри контролю

	Гранично допустимі концентрації/рекомендації			
	Результат	**ACGIH**	**NIOSH**	**OSHA**
Гуанідинтиоціанат	TWA	Не визначався	Не визначався	Не визначався

8.2 Контроль максимально допустимої концентрації

Інженерно-технічні заходи/засоби контролю Необхідно забезпечити добру загальну вентиляцію. Інтенсивність вентиляції повинна відповідати умовам. Якщо можливо, використовуйте ізольований робочий простір, місцеву витяжну вентиляцію та інші інженерно-технічні засоби для підтримання концентрації речовини в повітрі на рівні нижче максимально допустимої концентрації. Якщо рівень максимально допустимої концентрації не встановлено, підтримуйте прийнятні концентрації речовини в повітрі.

Індивідуальні засоби захисту

Захист органів дихання Очікується, що засоби захисту органів дихання не будуть потрібні, якщо матеріал використовується в звичайних умовах і з дотриманням рекомендацій. В іншому випадку дотримуйтесь рекомендацій по використанню респіраторів Управління охорони праці (OSHA) США, викладених в документі 29 CPP 1910.134, або Європейського стандарту EN 149. При перевищенні максимально допустимої концентрації або виявленні ознак ураження використовуйте респіратори, схвалені Національним інститутом з безпеки та гігієни праці (NIOSH) США, Управлінням з безпеки і охорони праці у видобувній промисловості (MSHA) США або Європейським стандартом EN 149.

Захист очей/обличчя Одягайте окуляри хімічного захисту.

Захист шкіри/тіла Одягайте захисний одяг

Захист навколишнього середовища Дотримуйтесь загальних рекомендацій роботи на об'єкті та утилізації відходів.

Скорочення
OSHA = Управління охорони праці, США
TWA = Середньозважена в часі концентрація, що обчислюється на основі впливу протягом 8 годин в день, 40 годин на тиждень.

Розділ 9: Фізичні та хімічні властивості

9.1 Інформація про фізичні та хімічні властивості

Опис матеріалу			
Фізична форма	Рідина	Зовнішній вигляд/Опис	Реагенти – це прозорі безбарвні рідини без запаху, які на первинному рівні є у буферних водних розчинах.
Колір	Прозора	Запах	Без запаху
Поріг відчуття запаху	Дані відсутні		
Загальні властивості			
Точка кипіння	100 °C (212 °F)	Температура плавлення/замерзання	0 °C (32 °F)
Температура розпаду	Дані відсутні	pH	3,5–8,8
Питома вага/відносна щільність	Дані відсутні	Розчинність у воді	Дані відсутні
В'язкість	Дані відсутні	Вибухові властивості	Дані відсутні
Окислювальні властивості:	Дані відсутні		
Волатильність			
Тиск парів	Дані відсутні	Щільність парів	Дані відсутні
Швидкість випаровування	Дані відсутні		
Вогненебезпечність			
	182,2222–293,3333 °C (360–560 °F) (реагент зв'язування)	ВМВ (Верхня межа вибуховості)	Дані відсутні
НМВ (Нижня межа вибуховості)	Дані відсутні	Самозаймання	Дані відсутні
Вогненебезпечність (в твердому, газоподібному стані)	Дані відсутні		
В навколишньому середовищі			
Коефіцієнт розподілення октанол/вода	Дані відсутні		

9.2 Додаткова інформація

Додаткові фізичні та хімічні властивості не виявлені.

Розділ 10: Стабільність і реакційна здатність

10.1. Реакційна здатність

В нормальних умовах використання небезпечні реакції невідомі.

10.2. Хімічна стабільність

Стабільно

10.3. Імовірність небезпечних реакцій

Небезпечна полімеризація не відбувається.

10.4. Умови, яких слід уникати

Несумісні матеріали. При спалюванні пластмасового картриджа, що містить реактиви, можуть вивільнятися токсичні побічні речовини.

10.5. Несумісні матеріали

Кислоти, окислювачі.

10.6. Небезпечні продукти розпаду

При спалюванні пластмасового картриджа, що містить реактиви, можуть вивільнятися токсичні речовини.

Розділ 11: Токсикологічна інформація

11.1. Інформація про токсикологічні наслідки

Компонент		
Гуанідинтиоціанат	593-84-0	**Гостра токсичність:** Внутрішньочеревно-миша LD50 • 593 mg/kg (мг/кг)

Властивості (ГУС)	**Класифікація**
Гостра токсичність	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Гостра токсичність - Перорально 5 - ATEmix (перорально) = 2965 mg/kg (мг/кг) **OSHA HCS 2012**•Дані відсутні
Роз'їдаюча/подразнююча дія на шкіру	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Незначне подразнення шкіри 3 **OSHA HCS 2012**•Дані відсутні
Серйозні пошкодження/подразнення очей	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Незначне подразнення очей 2B **OSHA HCS 2012**•Незначне подразнення очей 2B
Сенсибілізація шкіри	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Сенсибілізація органів дихання	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Небезпека при аспірації	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Карцерогенність	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Мутагенність для зародкових клітин	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Токсична дія на репродуктивну функцію	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Органоспецифічна токсичність при одноразовому впливі (STOT-SE)	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні
Органоспецифічна токсичність при багаторазовому впливі (STOT-RE)	**ЄС/CLP**•Дані відсутні **ГУС ООН 3**•Дані відсутні **OSHA HCS 2012**•Дані відсутні

Можливі наслідки для здоров'я

Вдихання	
Гострі наслідки	Можуть викликати подразнення.
Хронічні наслідки	Дані відсутні
Шкіра	
Гострі наслідки	Можуть викликати подразнення шкіри.
Хронічні наслідки	Дані відсутні
Очі	
Гострі (негайні) наслідки	Викликає подразнення очей.
Хронічні наслідки	Дані відсутні
Ковтання	
Гострі наслідки	Шкідливо в разі ковтання.
Хронічні наслідки	Дані відсутні

Скорочення
LD = летальна доза

Розділ 12: Інформація про вплив на навколишнє середовище

12.1. Токсичність

LC50 (лабораторні рибки): 89,1 mg/l (мг/л) @ 96 год

12.2. Стійкість і здатність до розпаду

Дані про матеріал відсутні.

12.3. Здатність до біоакумуляції

Дані про матеріал відсутні.

12.4. Мобільність у ґрунті

Дані про матеріал відсутні.

12.5. Результати оцінки відповідності ознакам «сталої біоакумулятивної токсичної речовини» і «дуже стійкої біоакумулятивної речовини»

Оцінка відповідності ознакам «сталої біоакумулятивної токсичної речовини» і «дуже стійкої біоакумулятивної речовини» не проводилася.

12.6. Інші небажані явища

Дослідження не проводились.

Розділ 13: Умови утилізації

13.1. Методи обробки відходів

Відходи продукту Утилізацію вмісту та (або) контейнера необхідно здійснювати відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

Відходи упаковки Утилізацію вмісту та (або) контейнера необхідно здійснювати відповідно до місцевих, регіональних, державних і (або) міжнародних норм.

13.2 Додаткова інформація

Біологічні зразки, пристрої для перенесення та використані картриджі слід вважати можливими переносниками збудників інфекційних захворювань, які вимагають дотримання стандартних заходів безпеки. Для правильної утилізації використаних картриджів і невикористаних реактивів дотримуйтеся прийнятих у вашому закладі правил захисту довкілля. Ці матеріали можуть мати властивості хімічно небезпечних відходів і вимагати виконання особливих державних або регіональних процедур для їх утилізації. Якщо прийняті в країні або регіоні правила не дають ясних указівок щодо правильної утилізації цих відходів, біологічні зразки та використані картриджі слід утилізувати з дотриманням правил ВООЗ (Всесвітньої організації охорони здоров'я) щодо поводження з медичними відходами та їх утилізації.

Розділ 14: Інформація щодо транспортування

	14.1 Номер ООН	14.2 Вантажне найменування ООН	14.3 Клас(и) небезпеки при транспортуванні	14.4 Група упаковки	14.5 Небезпека для навколишнього середовища
DOT	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується
TDG	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується
IMO/IMDG	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується
IATA/ICAO	Не регулюється	Не регулюється	Не регулюється	Не регулюється	Не стосується

14.6. Спеціальні заходи безпеки для користувачів

Не вказано.

14.7. Транспортування без тари відповідно до Додатку II MARPOL 73/78 і Кодексом IBC

Дані відсутні.

Розділ 15: Нормативна інформація

15.1 Правові акти в сфері безпеки, захисту здоров'я і навколишнього середовища/особливі правові акти, застосовні до речовини або суміші

Клас небезпеки SARA Гостра

Реєстр						
Компонент	**CAS**	**Канада, DSL**	**Канада, NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Гуанідинтиоціанат	593-84-0	Так	Ні	Так	Ні	Так

Паспорт з безпеки
Дата набрання чинності: Травень, 2020 р.
Заміняє версію документу від: Квітень 2020 р.

Xpert CT Assay
Xpert CT/NG Assay

Канада

Охорона праці

Канада - Інформаційна система щодо небезпечних матеріалів на робочих місцях (WHMIS) - Класифікація речовин

•Гуанідинтиоціанат	593-84-0	В списку не вказано

Канада - WHMIS - Перелік інгредієнтів, інформація про які підлягає розкриттю

•Гуанідинтиоціанат	593-84-0	В списку не вказано

Навколишнє середовище

Канада - Закон Канади про охорону навколишнього середовища (CEPA) - Список пріоритетних речовин

•Гуанідинтиоціанат	593-84-0	В списку не вказано

Сполучені Штати Америки

Охорона праці

США - Управління охорони праці (OSHA) - Забезпечення безпеки виробничого процесу - Високонебезпечні хімічні речовини

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - OSHA - Хімічні речовини, що підлягають особливому контролю

•Гуанідинтиоціанат	593-84-0	В списку не вказано

Навколишнє середовище

США - Закон про чисте повітря (CAA), 1990 - Небезпечні речовини, що забруднюють повітря

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - Акт про комплексне реагування, компенсації і відповідальності за шкоду навколишньому середовищу (CERCLA)/Закон про поліпшення фінансування та перерозподіл повноважень (SARA) - Небезпечні речовини та їх підзвітні кількості

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - CERCLA/SARA - Радіонукліди та їх підзвітні кількості

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - CERCLA/SARA - Розділ 302 Надзвичайно небезпечні речовини. Закон про планування дій при надзвичайних ситуаціях і право суспільства на інформацію (EPCRA) - підзвітні кількості

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - CERCLA/SARA - Розділ 302 Надзвичайно небезпечні речовини. Порогові заплановані кількості (TPQ)

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - CERCLA/SARA - Розділ 313 - Сповіщення про викиди

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - CERCLA/SARA - Розділ 313 - Список стійких біоакумулятивних токсичних речовин

•Гуанідинтиоціанат	593-84-0	В списку не вказано

США - Каліфорнія

Навколишнє середовище

США - Каліфорнія - Пропозиція 65 - Список карцерогенів		
•Гуанідинтиоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Ембріофетальна токсичність		
•Гуанідинтиоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Максимальні допустимі рівні дози (MADL)		
•Гуанідинтиоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Не несе значимого ризику (NSRL)		
•Гуанідинтиоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Репродуктивна токсичність - Вплив на жіночий організм		
•Гуанідинтиоціанат	593-84-0	В списку не вказано
США - Каліфорнія - Пропозиція 65 - Репродуктивна токсичність - Вплив на чоловічий організм		
•Гуанідинтиоціанат	593-84-0	В списку не вказано

15.2 Оцінка хімічної безпеки

Оцінка хімічної безпеки не проводилась.

Розділ 16: Додаткова інформація

Відповідні фрази (код і текст)

H302 – Шкідливо в разі ковтання
H313 – Може завдати шкоди у разі контакту зі шкірою
H320 – Викликає подразнення очей

Відмова від відповідальності/обмеження відповідальності

Представлені вище відомості базуються на доступних нам даних і вважаються вірними. В зв'язку з тим, що представлена інформація може бути використана в незалежних від нас та невідомих нам умовах, ми не несемо відповідальності за наслідки її використання, і всі особи, які отримують цю інформацію, повинні самостійно приймати рішення щодо наслідків застосування, властивостей, засобів захисту та способів утилізації відповідно до конкретних умов застосування. Ми не поручаємо, не даємо жодних гарантій та зобов'язань, явних або передбачуваних (включаючи гарантії придатності або товарної придатності для конкретної цілі), щодо матеріалів та точності даної інформації, отриманих при їх використанні результатів, а також небезпек, пов'язаних із використанням даного матеріалу. При поводженні з матеріалом та його використанні слід проявляти обережність. Представлена вище інформація передана добросовісно з упевненістю в її точності. Ми надаємо всю інформацію, що стосується передбачуваного використання матеріалу, станом на момент публікації. Однак, у разі небажаних наслідків, пов'язаних із даним продуктом, цей паспорт з безпеки продукту не є і не може бути заміною консультації з відповідним спеціалістом.

Скорочення
NDA = Дані відсутні

安全数据表
生效日期：2020 年 5 月
更换日期：2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

第 1 章：物质/混合物标识和公司/企业标识

1.1 产品标识符

产品名称	**Xpert CT Assay; Xpert CT/NG Assay**
产品代码	GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 物质或混合物的有关确定用途及其使用建议

有关确定用途	实验室使用

1.3 供应商安全数据表详情

制造商		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US：techsupport@cepheid.com
	电话（通用）	1 (888) 838-3222 - 美国（选 2）
	电话（通用）	1 (408) 541-4191 - 美国境外
供应商		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden www.cepheidinternational.com 欧盟: support@cepheideurope.com
	电话（通用）	33 563 825 319 - 欧盟

1.4 紧急电话号码

制造商	1 (800) 535-5053 - INFOTRAC - 24 小时紧急电话
制造商	1 (352) 323-3500 - 美国境外

第 2 章：危险标识

EU/EEC
根据：第 1272/2008 号规章（欧共体）(CLP)/REACH 1907/2006 [修订版 453/2010]

2.1 物质或混合物的分类

CLP	以下 SDS 适用于仅用于实验室的最终混合物成品。产品含有微珠和试剂，装于样品匣中或样品匣外的容器中。例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。 未分类

安全数据表
生效日期：2020 年 5 月
更换日期：2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

2.2 标签元素

CLP

危险声明 H302 -吞入有害。
H313 - 与皮肤接触可能有害
H320 - 导致眼睛刺激

防范声明

预防 P264 - 处理之后彻底清洗。
P270 - 使用本产品时，不要进餐、饮用或吸烟。

响应 P301 + P312 - 如果吞入：感到身体不适时，立即呼叫解毒中心或医生/医师。
P330 - 漱口。

贮存/处置 P501 - 与地方、区域、国家和/或国际法规的规定处置内容物和/或容器。

2.3 其他危害

CLP 依据第 1272/2008 号 (EC) 法规 (CLP)，此材料不属于有危害材料。

UN GHS 修订版 3 (使用于产品上的标签内容)

根据：联合国 (UN) 全球化学品统一分类和标签制度 (GHS)：第三次修订版

2.1 物质或混合物的分类

UN GHS
急性经口毒性 5
轻度皮肤刺激 5
轻度眼刺激 2B

2.2 标签元素

UN GHS

警告

危险声明 吞入有害。
导致眼睛刺激

防范声明

预防 操作之后要彻底清洗。

响应 如果发生皮肤刺激：获得医疗指导/就医治疗。
如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
如果眼睛刺激持续：获得医疗指导/就医治疗。
感到身体不适时，呼叫解毒中心或医生/医师。

贮存/处置 与地方、区域、国家和/或国际法规的规定处理内容和/或容器。

2.3 其他危险

UN GHS　　根据全球统一分类和标签制度（GHS），认为该产品是危险品。

美国（US）
根据：OSHA 29 CFR 1910.1200 HCS

2.1 物质或混合物的分类

OSHA HCS 2012　　轻度眼刺激 2B

2.2 标签元素

OSHA HCS 2012

危险声明　造成眼刺激
防范声明
预防　操作之后要彻底清洗。
响应　如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
如果眼睛刺激持续：获得医疗指导/就医治疗。
贮存/处置　与地方、区域、国家和/或国际法规的规定处理内容和/或容器。

2.3 其他危险

OSHA HCS 2012　　根据美国法规（29 CFR 1910.1200 - 危害通识标准），认为该产品属于非危险品。

加拿大
根据：WHMIS

2.1 物质或混合物的分类

WHMIS　　未分类

2.2 标签元素

WHMIS　　不要求标签元素。

2.3 其他危险

WHMIS　　在加拿大，根据工作场所有害物质信息系统（WHMIS），认为上述产品不是危害性物品。

2.4 其他信息

所有其他制剂、颗粒和其他组分的浓度在混合物中均低于 1%，或者根据美国危害通识法规 (29 CFR 1910.1200)、欧盟物质或混合物分类与标签指令或全球物质或混合物分类与标签统一制度均不被认为是危险物质。

安全数据表
生效日期：2020 年 5 月
更换日期：2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

第 3 章：成分构成/信息

3.1 物质

该材料不符合某种物质的标准。

3.2 混合物

构成					
化学名称	**标识符**	**%**	**LD50/LC50**	**按规章/指令分类**	**注解**
硫氰酸胍	**CAS：** 593-84-0 **EINECS：** 209-812-1	10% - 20%	593 mg/kg	**EU CLP：** 急性毒性 5、H302、H313、H320 **UN GHS：** 急性毒性 5（口服）；皮肤刺激 5；眼刺激 2B **OSHA HCS 2012：** 急性毒性 5（口服）；眼刺激 2B	NDA

第 4 章：急救措施

4.1 急救措施描述

吸入

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。将受害者移至新鲜空气处。如果呼吸困难，就施用氧气。如果受害者吸入该物质，就不要使用口对口方法；借助配备单向阀或其他适当的呼吸医疗设备的袖珍面罩来给予人工呼吸。如果受害者没有呼吸，就给予人工呼吸。

皮肤

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。对于轻微的皮肤接触，避免使物质扩散到未受影响的皮肤上。在与物质接触的情况下，立即用流动的水冲洗眼睛至少 20 分钟。脱掉并隔离受污染的衣物。

眼睛

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。在与物质接触的情况下，立即用大量的水冲洗眼睛至少 20 分钟。如果眼睛刺激持续：获得医疗指导/就医治疗。

摄入

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。如果吞入，用水漱口（只有当伤员意识清楚时）。切勿催吐。如果受害者摄入该物质，请勿使用口对口人工呼吸法。如果摄入，立即就医。

4.2 急性及缓发的最重要症状及效应

请参阅第 11 章 - 毒物学信息。

4.3 任何需要立即就医及特别治疗的症候

对医生的注释

所有治疗措施均应根据所观察到的患者的痛苦症状和体征进行。应考虑可能发生过度暴露于非本品材料的可能性。

第 5 章：消防措施

5.1 灭火介质

适用的灭火介质 大火：化学干粉、二氧化碳、抗溶性泡沫或喷水
小火：化学干粉，二氧化碳或喷水。

不适用的灭火介质 无可用数据

5.2 由物质或混合物产生的特殊危险

异常火灾和爆炸危险 盛装试剂的塑料检测盒可能会散发碳氧化物、硫氧化物、氮氧化物有毒蒸气。

有害燃烧产物 无可用数据

5.3 供消防队员采纳的建议

建筑消防员的防护服在火情中只能提供有限的保护；它在可能与物质直接接触的溢出情况下无效。
穿上制造商专门推荐的化学防护服。它可能提供很少或根本没有提供热保护。
配戴正压自给式呼吸装置 (SCBA)。
小火：如果能够无风险地完成，就从火区移出容器。

第 6 章：意外释放措施

6.1 个人预防措施、防护装备和紧急程序

个人预防措施 万一盒子断裂，则适用于这些个人预防措施。穿戴适当的防护服。切勿踩踏泄漏物。除非穿着适当的防护服，否则不要触碰损坏的容器或溢出的物质。使封闭的地区通风。

应急程序 如果在一般条件下并且按照推荐的方法使用材料，预计不必要执行应急程序。

6.2 环保预防措施

防止进入水道、下水道、地下室或封闭区域

6.3 用于遏制/净化的方法和材料

遏制/净化措施 对于少量撒漏，戴手套并用纸巾吸附撒漏物。切勿将撒漏的材料冲刷到排水管道中予以处置。

6.4 其他各章的参考

请参阅第 8 章 - 接触控制/个人防护以及第 13 章 - 处置注意事项。

第 7 章：操作和贮存

7.1 用于安全操作的预防措施

操作 无需任何特殊操作。如果盒子断裂，避免接触撒漏的试剂。

7.2 包括任何不相容性的安全贮存条件

贮存 按产品标签予以贮存。远离不相容材料。上锁贮存。将容器/包装在阴凉、通风良好之处保持密闭。

7.3 特定最终用途

请参阅第 1.2 条 - 有关确定用途。

第 8 章：接触控制/个人防护

8.1 控制参数

	接触限值/指南			
	结果	ACGIH	NIOSH	OSHA
硫氰酸胍	TWA	未确立	未确立	未确立

8.2 接触控制

工程措施/控制 应当使用良好的通用通风设施。通风速率应当与环境相配。如果适用，使用工艺外罩、局部排气通风或其它工程控制设施，以保持空气中的浓度低于推荐的接触限值。如果尚未确定接触限值，就将空气中的浓度保持在可接受的水平。

个人防护装备

呼吸 如果在一般条件下按照推荐方法使用材料，无需使用呼吸防护装置。否则，遵循 29 CFR 1910.134 或欧洲标准 EN 149 中的 OSHA 呼吸防护装置规定。如果超过接触限值或出现症状，就使用 NIOSH/MSHA 或欧洲标准 EN 149 认可的呼吸器。

眼睛/面部 佩戴防化学剂飞溅护目镜。

皮肤/身体 穿戴防护服

环境接触控制 遵守厂区管理和废物处置最佳规范。

略语表
OSHA = 职业安全和健康管理局
TWA = 时间加权平均值根据 8 小时/天、40 小时/周的接触量来确定

安全数据表
生效日期：2020 年 5 月
更换日期：2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

第 9 章：物理性质和化学性质

9.1 有关物理性质和化学性质的信息

材料描述			
外形	液体	外形/描述	试剂是清澈、无色的液体，无味，主要是没有臭味，主要是在水溶液中缓冲。
颜色	清澈	气味	无味
气味阈值	数据缺乏		
一般性质			
沸点	100 °C（212 °F）	熔点/凝固点	0 °C（32 °F）
分解温度	数据缺乏	pH 值	3.5 至 8.8
比重/相对密度	数据缺乏	水溶解度	数据缺乏
粘度	数据缺乏	易爆性质	数据缺乏
氧化性性质：	数据缺乏		
挥发性			
蒸气压力	数据缺乏	蒸气密度	数据缺乏
蒸发速率	数据缺乏		
易燃性			
	182.2222 至 293.3333 °C（360 至 560 °F（结合试剂）	爆炸上限	数据缺乏
爆炸下限	数据缺乏	自燃点	数据缺乏
易燃性（固体、气体）	数据缺乏		
环境方面			
辛醇/水分配系数	数据缺乏		

9.2 其他信息

未注明额外的物理和化学参数。

第 10 章：稳定性和反应性

10.1 反应性

在正常使用条件下，未知有危险反应。

10.2 化学稳定性

稳定

10.3 危险反应的可能性

不会发生危险的聚合反应。

10.4 应避免的情况

不相容的材料。燃烧盛装试剂的塑料检测盒可能会释放有毒副产物。

10.5 不相容的材料

酸、氧化剂。

10.6 危险的分解产物

燃烧盛装试剂的塑料检测盒可能会释放有毒副产物。

第 11 章：毒物学信息

11.1 有关毒物学效应的信息

组成成分		
硫氰酸胍	593-84-0	**急性毒性：** 腹腔-小鼠 LD50 593 mg/kg

GHS 危险种类	危险类别
急性毒性	EU/CLP•缺乏数据 UN GHS 3•急性毒性 - 口服 5 - ATEmix（口服） = 2965 mg/kg OSHA HCS 2012•缺乏数据
皮肤腐蚀/刺激	EU/CLP•缺乏数据 UN GHS 3•轻度皮肤刺激 3 OSHA HCS 2012•缺乏数据
严重眼损伤/刺激	EU/CLP•缺乏数据 UN GHS 3•轻度眼刺激 2B OSHA HCS 2012•轻度眼刺激 2B
皮肤过敏	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
呼吸过敏	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
吸入危险	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
致癌性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
生殖细胞致突变性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
针对生殖的毒性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-SE	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-RE	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据

潜在健康影响

吸入
急性（立即） 可能引起刺激。
慢性（缓发） 无可用数据
皮肤
急性（立即） 导致皮肤刺激。
慢性（缓发） 无可用数据
眼睛
急性（立即） 造成眼刺激。
慢性（缓发） 无可用数据
摄入
急性（立即） 如果吞入是有害的。
慢性（缓发） 无可用数据

略语表
LD = 致死剂量

第 12 章：生态学信息

12.1 毒性

LC50（孔雀鱼）：89.1 mg/L @ 96 小时

12.2 持久性和降解性

材料数据缺失。

12.3 生物累积的潜力

材料数据缺失。

12.4 土壤中的移动性

材料数据缺失。

12.5 PBT 及 vPvB 评估的结果

尚未进行 PBT 和 vPvB 评估。

12.6 其他不良效应

未发现研究成果。

第 13 章：处置注意事项

13.1 废物处理方法

产品废物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。
包装废弃物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。

13.2 其他信息

生物样本、转移设备以及用过的检测盒应被视为能够传播传染性病原体，必须采取标准预防措施。有关如何正确丢弃用过的检测盒和未使用过的试剂的信息，请遵循您所在机构的环境废物管理程序。这些材料可能会显示出需要为其执行特定的国家或地区的处置程序的化学危险废物的特性。如果国家或地区的法规没有明确的妥善处置规定，生物样本和使用过的检测盒应根据 WHO（世界卫生组织）的医疗废弃物处理和处置原则来处理。

第 14 章：运输信息

	14.1 UN 编号	14.2 UN 正式运输名称	14.3 运输危险分类	14.4 包装组	14.5 环境危害
DOT	未规定	未规定	未规定	未规定	不适用
TDG	未规定	未规定	未规定	未规定	不适用
IMO/IMDG	未规定	未规定	未规定	未规定	不适用
IATA/ICAO	未规定	未规定	未规定	未规定	不适用

14.6 用户特殊防护措施

未列明。

14.7 根据 MARPOL 73/78 的附件 II 以及 IBC 规范规定的散装运输

缺乏数据。

第 15 章：法规信息

15.1 针对特定物质或混合物的安全、卫生和环境条例/法规

SARA 危险性分类 急性

名录						
成分	CAS	加拿大 DSL	加拿大 NDSL	欧盟 EINECS	欧盟 ELNICS	TSAC
硫氰酸胍	593-84-0	是	否	是	否	是

安全数据表

生效日期：2020 年 5 月
更换日期：2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

加拿大

劳动

加拿大 - 加拿大工作场所危险物质信息系统 (WHMIS) - 物质分类

•硫氰酸胍	593-84-0	未列出

加拿大 - 加拿大工作场所危险物质信息系统 (WHMIS) - 组分披露列表

•硫氰酸胍	593-84-0	未列出

环境

加拿大 - 环境保护法 (CEPA) - 优先重点物质列表

•硫氰酸胍	593-84-0	未列出

美国

劳动

美国 - 职业安全与健康管理局 (OSHA) - 制程安全管理 - 高度危险化学品

•硫氰酸胍	593-84-0	未列出

美国 - 职业安全与健康管理局 (OSHA) - 专门监管化学品

•硫氰酸胍	593-84-0	未列出

环境

美国 - CAA（清洁空气法）- 1990 年危险空气污染物

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 危险物质及其可报告数量

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 放射性核素及其可报告数量

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质 EPCRA 可报告数量

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质计划限制数量

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - 排放报告

•硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - PBT 化学品列表

•硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚

环境

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 致癌物清单

•硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 发育毒性

•硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 最大容许剂量水平 (MADL)

•硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 无显著风险级别 (NSRL)

•硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 女性

•硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 男性

•硫氰酸胍	593-84-0	未列出

15.2 化学安全评估

未进行化学安全评估。

第 16 章：其他信息

相关习语（规范及全文）

H302 - 吞入有害
H313 - 与皮肤接触可能有害
H320 - 导致眼睛刺激

免责声明/责任声明

以上信息基于对于我们的可用数据，而且相信是正确的。由于对信息的应用可能会在超出我们控制的条件下和以我们所不熟悉的条件进行，因此我们对其使用的任何结果概不承担任何责任，而且收到此信息的所有人士均务必自行确定其特定应用条件下的效能、性能、防护和处置方法。未就信息所涵盖的材料、其准确性、因使用材料而获得的结果或与使用材料相关的危害作出任何明示或暗示的表示、担保或保证（包括对特定目的下适用性或适销性的担保）。操作或使用本材料应小心谨慎。以上信息以诚信提供，而且相信是准确的。截至签发日期，我们提供有关可预见材料操作的所有信息。然而，一旦发生与本品相关的恶性事故，本安全数据表却不是，而且也不旨在是向接受过适当训练人员咨询的替代。

略语表

NDA = 无可用数据

安全性データシート
発効日:2020 年 5 月
優先日付:2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

セクション 1:物質混合物、および企業事業の識別

1.1 製品識別子

製品名 **Xpert CT Assay; Xpert CT/NG Assay**
製品コード GXCT-CE-10、GXCT/NG-10、GXCT/NG-CE-10、GXCT/NG-120、GXCT/NG-CE-120、GXCT/NGX-CE-10、GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 物質や混合物の特定された関連用途、および推奨されない用途

特定された関連用途 研究用

1.3 安全データを提供した供給業者の詳細

製造業者 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US: techsupport@cepheid.com
電話(一般) 1 (888) 838-3222 – 米国オプション 2
電話(一般) 1 (408) 541-4191 – 米国外

供給業者 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
EU: support@cepheideurope.com
電話(一般) 33 563 825 319 - EU

1.4 緊急電話番号

製造業者 1 (800) 535-5053 - INFOTRAC - 24 時間緊急電話
製造業者 1 (352) 323-3500 – 米国外

セクション 2:危険性識別

EU/EEC

準拠: 指令(EC)1272/2008 (CLP)/REACH 1907/2006 [453/2010 による改訂]

2.1 物質や混合物の分類

CLP 次の SDS は、研究所で使用される最終完全混合物製品用のみです。本製品は、カートリッジまたは装置外の容器内にビーズおよび試薬を含んでいます。一部の物質の情報の開示の免除は、CLP 項目 1(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)に従っています。
未分類

2.2 ラベル要素

CLP

危険有害性情報 H302 –飲み込むと有害。
H313 – 皮膚に付着すると有害な可能性
H320 – 眼への刺激を引き起こす

予防情報

予防 P264 – 取り扱いの後、十分に洗う。
P270 – この製品を使用している間は飲食や喫煙をしない。

応答 P301+312 – 飲み込んだ場合:気分が悪い場合、直ちに毒物センターあるいは医師に連絡する。
P330 – 口をゆすぐ。

保管・処分 P501 – 地方、地域、国、および/または国際的な規則に従って中身および/または容器を廃棄してください。

2.3 その他危険性

CLP 規定(EC) No. 1272/2008 (CLP) に準じて、本剤は危険物とみなされません。

UN GHS 改訂第 3 版 (製品に使用されている表示の内容)

準拠: UN 化学品の分類および表示に関する世界調和システム(GHS) 改訂第 3 版

2.1 物質や混合物の分類

UN GHS

急性毒性 経口 5
軽度の皮膚刺激 5
軽度の眼刺激2B

2.2 ラベル要素

UN GHS

警告

危険有害性情報 飲み込むと有害。皮膚に付着すると有害な可能性
眼への刺激を引き起こす

予防情報

予防 取り扱いの後、十分に洗う。

応答 皮膚に刺激が生じた場合:医師の助言/手当てを受ける。
目に入った場合:数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目の刺激が続く場合:医師の助言/手当てを受ける。
気分が悪い場合、毒物センターあるいは医師に連絡する。

保管・処分 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器を廃棄してください。

2.3 その他危険性

UN GHS 危険化学品分類表示の世界調和システム(GHS)では、本製品は危険な物質と考慮されています。

米国(US)
準拠: OSHA 29 CFR 1910.1200 HCS

2.1 物質や混合物の分類

OSHA HCS 2012 軽度の眼刺激2B

2.2 ラベル要素

OSHA HCS 2012

危険有害性情報 眼への刺激を引き起こす

予防情報

予防 取り扱いの後、十分に洗う。

応答 目に入った場合:数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目の刺激が続く場合:医師の助言/手当てを受ける。

保管・処分 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器を廃棄してください。

2.3 その他危険性

OSHA HCS 2012 米国規定(29 CFR 1910.1200 - 危険有害性周知基準)に基づき、本製品は危険物とみなされません。

カナダ
準拠: WHMIS

2.1 物質や混合物の分類

WHMIS 未分類

2.2 ラベル要素

WHMIS ラベル要素は必要ありません。

2.3 その他危険性

WHMIS カナダでは、上述の製品は作業場にある危険物に関する情報システム (WHMIS)に基づき危険物とみなされません。

2.4 その他情報

その他のすべての試薬、ビーズ、その他の成分は、混合物の 1%未満であるか、または米国ハザード通信規制(29 CFR 1910.1200)、物質または混合物の分類と表示に関する EU 指令、または物質または混合物の分類と表示に関する世界調和システムで有害とみなされていない。

セクション 3:成分の組成・情報

3.1 物質

本剤は、材料区分を満たしません。

3.2 混合物

合成物					
化学名	**識別子**	**%**	**LD50/LC50**	**規定/指針に基づく分類**	**コメント**
チオシアン酸グアニジン	**CAS:**593-84-0 **EINECS:**209-812-1	10%～20%	593 mg/kg	**EU CLP:**急性毒性 5、H302、H313、H320 **UN GHS:**急性毒性 5(経口)、皮膚のかゆみ 5、目のかゆみ 2B、 **OSHA HCS 2012:**急性毒性 5(経口)、目のかゆみ 2B	NDA

セクション 4:応急処置手段

4.1 応急措置手段

吸引

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。被災者を新鮮な空気がある場所に移す。呼吸困難の場合は酸素を供給する。被災者が物質を吸引した場合、口移し式人工呼吸を行ってはならない; 一方向バルブの付いたポケットマスクや、その他の適切な呼吸医療装置を使って人工呼吸を行う。被災者が呼吸していない場合は、人工呼吸を施す。

皮膚

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。軽度の皮膚との接触では、影響を受けていない皮膚に物 質を広げないようにする。物質と接触した場合は、最低 20 分間、直ちに流水で皮膚を洗浄する。汚染した衣類を取り除いて隔離する。

目

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。物質と接触した場合は、最低 20 分間、直ちに流水で目を洗浄する。目の刺激が続く場合:医師の助言/手当てを受ける。

摂取

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。飲み込んだ場合は、水で口をゆすいではならない(意識がある場合)。嘔吐を誘発しないでください。被災者が物質を摂取した場合は口移し式人工呼吸を行ってはならない。摂取した場合は直ちに医師の手当てを受ける。

4.2 もっとも重要な症状と影響、急性および遅発性

第十一項　毒性に関する情報を参照してください。

4.3 直ちに医学的配慮と特別治療を必要とする兆候

医師へのメモ

治療はすべて、患者の苦痛の兆候および症状に基づき行われる必要があります。本製品以外の物質に著しくさらされた可能性について考慮する必要があります。

セクション 5:消化手段

5.1 消火剤

適切な消火剤 大規模火災:乾燥した化学品、二酸化炭素、耐アルコール泡消火剤、散水
小規模火災:乾燥した化学品、二酸化炭素、散水

不適切な消火剤 データなし

5.2 物質や混合物から発生する特別な危険

異常な火災と爆発の危険 試薬を含むプラスチック製カートリッジは、炭素酸化物、硫黄酸化物、窒素酸化物の有毒な蒸気を放出することがあります。

有害な燃焼生物 データなし

5.3 消防士への助言

建物火災用消防用服が火災状況で提供する保護は限定されている; 流出した状況では物質に直接接触する可能性があるため、効果がない。
製造業者が推奨する化学品防護服を着用する。熱に対する保護は、ある程度、またはまったく提供されない。
陽圧自給式呼吸器(SCBA)を着用する。
小規模火災: 危険を冒さずにできる場合は、火災区域 から容器を移動させる動かす。

セクション 6:漏出時の措置

6.1 人体に対する注意事項、保護具、および緊急時措置

人体に対する注意事項 カートリッジが破損した場合、これらの人体に対する予防措置が適用されます。適切な保護服を着用する。漏出した物質を通って歩かない。適切な保護服を着用せずに破損した容器または漏出した物質に触れてはならない。閉じ込められた場所を換気する。

応急措置 物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されない。

6.2 影響に対する注意事項

水路、下水道、地下室、囲まれた区域に流入するのを防ぐ。

6.3 閉じ込めと清掃の手段と物質

閉じ込めと清掃の手段 少量の流出の場合は、手袋を着用し、ペーパータオルで流出を吸収してください。流出した物質を排水溝に廃棄しないでください。

6.4 他のセクションへの言及

第八項 爆発管理/安全保護、および第十三項 廃棄時の注意事項を参照してください。

セクション 7:取り扱いと保管

7.1 安全な取り扱いについての注意

取り扱い

特別な取扱いは必要ありません。カートリッジが破損した場合、漏出した試薬に触れないようにしてください。

7.2 安全な保管の条件、不適合性を含む

保管

製品ラベルに従って保管してください。互換性をもたない物質から離す。鍵をかけて保管する。容器/パッケージをしっかりと密閉し、涼しく、風通しの良い場所に保管してください。

7.3 具体的な最終用途

セクション 1.2 関連する使用方法に関する情報を参照してください。

セクション 8:暴露管理・個人保護

8.1 管理パラメータ

	曝露限度／ガイドライン			
	結果	ACGIH	NIOSH	OSHA
グアニジンチオシアネート	TWA	設定なし	設定なし	設定なし

8.2 曝露管理

工学的手段・管理

十分な通気を確保してください。通規率は状況に応じて適切に調整してください。該当する場合は、包囲装置、局所排気装置、またはその他のエンジニアリングコントロール装置を使って、空気中の粉塵レベルが推奨暴露限界を超えないようにしてください。暴露レベルが確定されていない場合は、許容範囲の粉塵量を維持してください。

個人用保護具

呼吸器官

物質が通常の状況でかつ推奨通りに使用される場合、呼吸装置が必要であることは予測されません。もし必要な場合、OSHA 呼吸器規制に関しては、29 CFR 1910.134 または 欧州標準 EN 149 をご覧ください。暴露基準を超える場合、あるいは症状が発症した場合は、NIOSH/MSHA または 欧州標準 EN 149 保護マスクをご使用ください。

目・顔面

化学物飛散防止ゴーグルを着用してください。

皮膚・人体

保護服を着用してください。

環境暴露管理

現場管理および廃棄物の取り扱いは十分注意して行ってください。

略語について
OSHA = 労働安全衛生局
TWA = 時間加重平均値は、8 時間/1 日、40 時間/1 週間の暴露に基づいた数値です。

セクション 9:物理的および化学的特性

9.1 物理的および化学的特性

材料の説明			
物理的形状	液体	外観/記述	試薬は、主に水溶液で緩衝された、透明、無色、無臭の液体である。
色	透明	臭気	無臭
臭気限界	データ不足		
一般的性質			
沸騰点	100°C(212°F)	融解点・凝固点	0°C(32°F)
分解温度	データ不足	pH	3.5～8.8
比重・相対密度	データ不足	水溶性	データ不足
粘性	データ不足	爆発特性	データ不足
酸化特性:	データ不足		
揮発度			
蒸気圧	データ不足	蒸気密度	データ不足
蒸発速度	データ不足		
可燃性			
	182.2222～293.3333°C (360°F～560°F)(結合試薬)	UEL	データ不足
LEL	データ不足	自己発火	データ不足
可燃性(固体、ガス)	データ不足		
環境曝露管理			
オクタノール・水分配係数	データ不足		

9.2 その他情報

その他に物理的および化学的パラメータの記載はありません。

セクション 10:安定性と反応性

10.1 反応性

通常の使用において、危険反応は報告されていません。

10.2 化学安定性

安定

10.3 有害反応の可能性

危険物のポリメリゼーションは発生しません。

10.4 回避すべき条件

不適合物質。試薬を含むプラスチック製カートリッジを燃焼すると、毒性の副産物を放出する可能性があります。

10.5 不適合物質

酸、酸化試薬。

10.6 有害分解性生物

試薬を含むプラスチック製カートリッジを燃焼すると、毒性の副産物を放出する可能性があります。

セクション 11:毒性情報

11.1 毒性効果

成分		
グアニジンチオシアネート	593-84-0	**急性毒性:**腹腔内-マウス LD50・593 mg/kg

GHS 特性	分類
急性毒性	EU/CLP-データ不足 UN GHS 3-急性毒性 - 経口 5 - ATEmix(経口)= 2965 mg/kg OSHA HCS 2012-データ不足
皮膚の腐食・炎症	EU/CLP-データ不足 UN GHS 3-軽度の皮膚刺激 3 OSHA HCS 2012-データ不足
重度の目の損傷・炎症	EU/CLP-データ不足 UN GHS 3-軽度の眼刺激 2B OSHA HCS 2012-軽度の眼刺激 2B
皮膚感作性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
呼吸器感作性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
吸引有害性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
発癌性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
生殖細胞変異原性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
生殖毒性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
STOT-SE	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
STOT-RE	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足

考えられる健康への影響

吸引
急性(即座) 過敏症が生じる場合があります。
慢性(遅発性) データなし
皮膚
急性(即座) 皮膚に炎症を起こす。
慢性(遅発性) データなし
目
急性(即座) 目の炎症を起こす。
慢性(遅発性) データなし
摂取
急性(即座) 飲み込んだ場合、健康に支障を生じる。
慢性(遅発性) データなし

略語について
LD = 致死量

セクション 12:生態学的情報

12.1 毒性

LC50(グッピー):96 時間で 89.1 mg/L

12.2 持続性と分解性

実態データが不足しています。

12.3 生体内蓄積能

実態データが不足しています。

12.4 土壌中移動性

実態データが不足しています。

12.5 PBT と vPvB 評価の結果

PBT および vPvB アセスメントは行われていません。

12.6 その他有害影響

そのような研究結果はありません。

セクション 13:廃棄上の注意

13.1 廃棄物処理手段

製品廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

包装廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

13.2 その他情報

生物検体、移動器具および使用済みカートリッジは、標準的予防策を必要とする感染体(病原菌)を伝播する可能性があると見なしてください。使用済みカートリッジや、未使用の試薬の適切な廃棄については、当該施設の環境廃棄物手順に従ってください。これらは、国や地域の特別な廃棄手順に従う必要のある化学品有害廃棄物の特徴を示す可能性があります。国の法律や地域の条例により、適切な廃棄処理について、明確な指示が出されていない場合、生物検体や使用済みカートリッジは WHO(世界保健機関)の医療廃棄物の取り扱いおよび廃棄についてのガイドラインに従って廃棄してください。

セクション 14:輸送情報

	14.1 UN 番号	14.2 UN 正式輸送品目名	14.3 輸送有害性等級	14.4 包装等級	14.5 環境有害性
DOT	規制なし	規制なし	規制なし	規制なし	該当なし
TDG	規制なし	規制なし	規制なし	規制なし	該当なし
IMO/IMDG	規制なし	規制なし	規制なし	規制なし	該当なし
IATA/ICAO	規制なし	規制なし	規制なし	規制なし	該当なし

14.6 ユーザーに対する特別予防装置

指定なし。

14.7 MARPOL 73/78 附属書 II と IBC コードに則ったバルク輸送

データ不足。

安全性データシート
発効日:2020 年 5 月
優先日付:2020 年 4 月

Xpert CT Assay
Xpert CT/NG Assay

セクション 15:規制情報

15.1 物質や混合物についての具体的な安全、健康、環境規制・法律

SARA 危険分類 急性

在庫						
成分	CAS	カナダ DSL	カナダ NDSL	EU EINECS	EU ELNICS	TSCA
グアニジンチオシアネート	593-84-0	あり	なし	あり	なし	あり

カナダ

作業

カナダ - WHMIS - 物質の分類

·グアニジンチオシアネート	593-84-0	掲載外

カナダ - WHMIS - 成分開示リスト

·グアニジンチオシアネート	593-84-0	掲載外

環境

カナダ - CEPA - 優先物質リスト

·グアニジンチオシアネート	593-84-0	掲載外

米国

作業

米国 - OSHA - プロセス安全管理 - 非常に危険有害な化学品

·グアニジンチオシアネート	593-84-0	掲載外

米国 - OSHA - 特異制御化学物質

·グアニジンチオシアネート	593-84-0	掲載外

環境

米国 - CAA (大気汚染防止法) - 1990 有害大気汚染物質

·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 有害危険物質および報告基準量

·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 放射性核種および報告義務量

·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第 302 項 - 極めて有害な物質 EPCRA の報告義務量

·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第 302 項 - 極めて有害な物質 TPQ

·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第 313 項 - 排気量レポート

·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA 第 313 項 排出報告

·グアニジンチオシアネート	593-84-0	掲載外

米国 – カリフォルニア

環境

米国 – カリフォルニア – 州住民投票事項 65-発がん性物質リスト		
·グアニジンチオシアネート	593-84-0	掲載外
米国 – カリフォルニア – 州住民投票事項 65-発達毒性		
·グアニジンチオシアネート	593-84-0	掲載外
米国 – カリフォルニア – 州住民投票事項 65-最大許容レベル(MADL)		
·グアニジンチオシアネート	593-84-0	掲載外
米国 – カリフォルニア – 州住民投票事項 65-無リスク(安全)摂取量(NSRL)		
·グアニジンチオシアネート	593-84-0	掲載外
米国 – カリフォルニア – 州住民投票事項 65-生殖毒性-女性		
·グアニジンチオシアネート	593-84-0	掲載外
米国 – カリフォルニア – 州住民投票事項 65-生殖毒性-男性		
·グアニジンチオシアネート	593-84-0	掲載外

15.2 化学物質安全評価

化学的安全評価は実施されていません。

セクション 16:その他情報

関連するフレーズ (コードと全テキスト)

H302 – 飲み込むと有害
H313 – 皮膚に付着すると有害な可能性
H320 – 眼への刺激を引き起こす

免責条項/責任声明

上記の情報は、私たちに利用可能なデータに基づいており、正確であると考えられています。それを受け取るすべての人は、その効果、属性、保護、廃棄についてそれぞれの特定の条件に従って各自の判断を行う必要があります。その物質、この情報の正確性、その使用による結果、または物質の使用に関連する危険については、(特定の目的への適合や商品性の保証を含む)明示的または暗黙の表明、保証を行うものではありません。この物質の取り扱いおよび使用には、注意が必要です。上記の情報は誠実に提供されたものであり、正確であると信じられています。発行日付けで、本資料で予見できる取扱いに関連するすべての情報を提供しています。しかし、本製品に関連して不都合な事故が起きた場合、この安全性データシートは適切な訓練を受けた担当者との協議に代わるものとして意図しているものではありません。

略語について
NDA = 該当データなし。

Säkerhetsdatablad
Giltighetsdatum: Maj, 2020
Ersätter datum: April, 2020

Xpert CT Assay
Xpert CT/NG Assay

Avsnitt 1: Namn på ämnet/blandningen och bolaget/företaget

1.1 Produktidentifierare

Produktnamn **Xpert CT Assay; Xpert CT/NG Assay**

Produktkod GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Relevant identifierade användning av ämnet eller blandningen och användningar som det avråds från

Relevant identifierade användning(ar) Laboratorieanvändning

1.3 Detaljer om säkerhetsdatabladets leverantör

Tillverkare Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA
www.cepheid.com
USA: techsupport@cepheid.com

Telefon (allmän) 1 (888) 838-3222 – USA alt. 2

Telefon (allmän) 1 (408) 541-4191 – Utanför USA

Leverantör Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sverige
www.cepheidinternational.com
EU: support@cepheideurope.com

Telefon (allmän) 33 563 825 319 – EU

1.4 Larmnummer

Tillverkare +1 (800) 535-5053 – INFOTRAC – hela dygnet, nödsituation

Tillverkare 1 (352) 323-3500 – Utanför USA

Avsnitt 2: Farliga egenskaper

EU/EEG

Enligt: Förordning (EG) nr 1272/2008 (CLP)/REACH 1907/2006 [ändrad genom 453/2010]

2.1 Klassificering av ämnet eller blandningen

CLP Följande säkerhetsdatablad avser endast den färdiga blandningsprodukten som den används i laboratorium. Produkten innehåller pärlor och reagens i kassetten eller i separata behållare. Undantag för att avslöja någon komponentinformation gäller enligti enlighet med CLP artikel 1(5)(d) och 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Inte klassificerad

2.2 Märkta element

CLP

Faroangivelser	H302 – Skadligt vid förtäring H313 – Kan vara skadligt vid hudkontakt H320 – Orsakar ögonirritation.
Skyddsangivelser	
Förebyggande	P264 – Tvätta grundligt efter hantering. P270 – Ät inte, drick inte och rök inte när du använder produkten.
Svar	P301+P312 – VID FÖRTÄRING: Vid obehag, kontakta omedelbart GIFTINFORMATIONSCENTRAL eller läkare. P330 – Skölj munnen.
Förvaring/avfall	P501 – Avyttra innehåll och/eller behållaren i enlighet med lokala, regionala, nationella och/eller internationella förordningar.

2.3 Övriga faror

CLP Enligt förordning (EG) Nr 1272/2008 (CLP) anses detta material inte vara farligt.

FN GHS Revidering 3 (Etiketteringsinnehåll som används på produkter)

Enligt: Förenta Nationernas Globally Harmonized Standard of Classification and Labeling of Chemicals (GHS, globalt harmoniserat system för klassificering och märkning av kemikalier): Tredje reviderade utgåvan

2.1 Klassificering av ämnet eller blandningen

FN GHS

Akut toxicitet – oral 5
Mild hudirritation 5
Mild ögonirritation 2B

2.2 Märkningsuppgifter

FN GHS

VARNING

Faroangivelser	Skadligt vid förtäring Kan vara skadligt vid hudkontakt Orsakar ögonirritation
Skyddsangivelser	
Förebyggande	Tvätta noggrant efter hantering.
Svar	Vid hudirritation: Sök läkarhjälp. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja. Vid bestående ögonirritation: Sök läkarhjälp. Vid obehag, kontakta GIFTINFORMATIONSCENTRAL eller läkare.
Förvaring/avfall	Avyttra innehållet och/eller behållaren i enlighet med lokala, regionala, nationella och/eller internationella förordningar.

2.3 Andra faror

FN GHS Enligt Globally Harmonized Standard for Classification and Labeling (GHS, globalt harmoniserat system för klassificering och märkning av kemikalier) anses den här produkten vara farlig.

Förenta staterna (USA)
Enligt: OSHA 29 CFR 1910.1200 HCS

2.1 Klassificering av ämnet eller blandningen

OSHA HCS 2012 Mild ögonirritation 2B

2.2 Märkta element

OSHA HCS 2012

Faroangivelser Orsakar ögonirritation

Skyddsangivelser

Förebyggande Tvätta noggrant efter hantering.

Svar VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja.
Vid bestående ögonirritation: Sök läkarhjälp.

Förvaring/avfall Avyttra innehållet och/eller behållaren i enlighet med lokala, regionala, nationella och/eller internationella förordningar.

2.3 Andra faror

OSHA HCS 2012 Enligt United States Regulations (29 CFR 1910.1200 – Riskkommunikationsstandard), anses produkten inte vara farlig.

Kanada
Enligt: WHMIS

2.1 Klassificering av ämnet eller blandningen

WHMIS Inte klassficerad

2.2 Märkta element

WHMIS Inga märkta element erfordras.

2.3 Andra faror

WHMIS I Kanada anses produkten som nämns ovan inte vara en riskprodukt enligt Workplace Hazardous Materials Information System (WHMIS) (Material informationssystem för arbetsplatsrisker).

2.4 Övrig information

Alla andra reagenser, kulor, och andra beståndsdelar har koncentrationer mindre än 1 % i blandningen eller anses inte farliga enligt amerikanska regler för riskkommunikation (29 CFR 1910.1200), EU-direktiv för klassificering och märkning av ämnen eller blandningar eller Global Harmonization System för klassificering och märkning av ämnen eller blandningar.

Avsnitt 3: Sammansättning/Information om beståndsdelar

3.1 Ämnen

Materialet uppfyller inte kriterierna för ett ämne.

3.2 Blandningar

Sammansättning					
Kemiskt namn	**Identifierare**	**%**	**LD50/LC50**	**Klassificeringar enligt förordning/direktiv**	**Kommentarer**
Guanidintiocyanat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10 % till 20 %	593 mg/kg	**EG CLP:** Akut tox. 5, H302, H313, H320 **FN GHS:** Akut tox. 5 (orl); Hudirrit. 5; Ögonirrit. 2B **OSHA HCS 2012:** Akut tox. 5 (orl); Ögonirrit. 2B	Inga data tillgängliga

Avsnitt 4: Åtgärder vid första hjälpen

4.1 Beskrivning av åtgärder vid första hjälpen

Inandning Det förväntas inget behov av första hjälpen om materialet används under normala omständigheter och rekommenderat. För personen till frisk luft. Ge syrgas vid besvärad andning. Använd inte mun mot mun metoden om den drabbade inandat ämnet, ge konstgjord andning med pocketmask utrustad med en envägsventil eller med annan lämplig medicinsk andningsutrustning. Ge konstgjord andning om den drabbade inte andas.

Hud Det förväntas inget behov av första hjälpen om materialet används under normala omständigheter och rekommenderat. Vid mindre hudkontakt, undvik att sprida materialet på opåverkad hud. Vid kontakt med ämnet, skölj huden omedelbart med rinnande vatten i minst 20 minuter. Ta bort kontaminerad klädsel.

Ögon Det förväntas inget behov av första hjälpen om materialet används under normala omständigheter och rekommenderat. Vid kontakt med ämnet, skölj ögonen omedelbart med rinnande vatten i minst 20 minuter. Vid bestående ögonirritation: Sök läkarhjälp.

Förtäring Det förväntas inget behov av första hjälpen om materialet används under normala omständigheter och rekommenderat. Vid förtäring skölj munnen med vatten (endast om personen är vid medvetande). Framkalla INTE kräkning. Använd inte mun mot mun metoden om den drabbade svalt ämnet. Sök läkarvård omedelbart vid förtäring.

4.2 De viktigaste symptomen och effekterna, både akuta och fördröjda

Se avsnitt 11 – Toxikologisk information.

4.3 Indikation på omedelbar medicinsk vård och specialbehandling vid behov

Läkaranvisningar Alla behandlingar bör baseras på observerade tecken och symtom på obehag hos patienten. Hänsyn bör tas till möjligheten att överexponering för andra material än den här produkten material kan ha skett.

Avsnitt 5: Brandbekämpningsåtgärder

5.1 Släckmedel

Lämpliga släckmedel STORA BRÄNDER: Torr kemikalie, CO2, alkoholresistent skum eller vattenspray.
MINDRE BRÄNDER: Torra kemikalier, CO2 eller vattenspray.

Olämpliga bekämpningsmedel Inga data tillgängliga

5.2 Särskilda faror som upp står hos ämnet eller blandningen

Ovanliga brand- eller explosionsrisker Plastkassetter som innehåller reagenser kan avge giftiga ångor av koloxider, svaveloxider, kväveoxider.

Farliga förbränningsprodukter Inga data tillgängliga

5.3 Råd till brandbekämpningspersonal

Skyddskläsel för brandmän som bekämpar bränder i byggnadskonstruktioner ger ENDAST begränsat skydd vid brandsituationer; den fungerar inte vid spillsituationer där direktkontakt med materialet kan förekomma.
Använd kemisk skyddskläsel specifikt rekommenderad av tillverkaren. Den kan ge lite eller inget termiskt skydd.
Använd alltid sluten andningsapparat med övertryck (SCBA).
MINDRE BRÄNDER: Flytta behållare från brandområdet om det är möjligt utan risk.

Avsnitt 6: Åtgärder vid oavsiktliga utsläpp

6.1 Personliga försiktighetsåtgärder, skyddsutrustning och förfaranden i nödsituationer

Personliga försiktighetsåtgärder I den händelse att kassetten är trasig är dessa personliga försiktighetsåtgärder tillämpliga. Använd lämplig skyddskläsel. Gå inte genom spillt material. Rör inte skadade behållare eller spillt material utan lämplig skyddskläsel. Ventilera stängda utrymmen.

Förfaranden i nödsituationer Inga nödsituationsprocedurer förväntas bli nödvändiga om materialet används under vanliga omständigheter och enligt rekommendationer.

6.2 Miljömässiga säkerhetsåtgärder

Förhindra spridning till vattenvägar, avlopp, källare eller slutna utrymmen.

6.3 Metoder och material för inneslutning och sanering

Inneslutning/ saneringsåtgärder För mindre spill, använd handskar och absorbera spill med pappershandduk. Avyttra inte spillt material i avlopp.

6.4 Referenser till andra avsnitt

Se avsnitt 8 – Exponeringskontroll/personligt skydd och avsnitt 13 – Avfallshantering.

Avsnitt 7: Hantering och lagring

7.1 Försiktighetsåtgärder för säker hantering

Hantering Ingen särskild hantering är nödvändig. Undvik kontakt med utspillda reagenser om en kassett är trasig.

7.2 Förhållanden för säker lagring, inklusive eventuell oförenlighet

Förvaring Förvara enligt produktmärkning. Håll borta från inkompatibla material. Förvaras inlåst. Förvara behållare/förpackning väl tillsluten, svalt och med ordentlig ventilation.

7.3 Specifik slutanvändning(ar)

Se avsnitt 1.2 – Identifierade relevanta användningar.

Avsnitt 8: Begränsning av exponeringen/personligt skydd

8.1 Kontrollparametrar

	Gränsvärden/riktlinjer för exponering			
	Resultat	**ACGIH**	**NIOSH**	**OSHA**
Guanidintiocyanat	TWA	Ej fastställt	Ej fastställt	Ej fastställt

8.2 Kontroller av exponering

Tekniska åtgärder/kontroller Ordentlig ventilation skall ombesörjas. Ventilationshastigheten ska överensstämma med situationen. Om tillämpligt använd processinneslutning, punktutsug eller andra tekniska åtgärder som håller luftburna nivåer under rekommenderade exponeringsgränser. Om exponeringsgränsen inte fastställts, håll luftburna nivåer på en acceptabel nivå.

Personlig skyddsutrustning

Respiratoriska Det förväntas inget behov av andningsutrustning om materialet används under normala omständigheter och enligt det som är rekommenderat. Om det ändå används ska OSHA-reglerna för andningsutrustning följas i enlighet med 29 CFR 1910.134 eller European Standard EN 149. Använd NIOSH/MSHA eller European Standard EN 149 godkänd andningsutrustning om exponeringsgränserna överskrids eller symptom förekommer.

Ögon/ansikte Använd stänkskyddsglasögon för kemikalier.

Hud/kropp Använd skyddsklädsel

Begränsning av miljöexponeringen Följ bästa praxis för platshantering och avfallshantering.

Nyckeln till förkortningar
OSHA = Occupational Safety and Health Administration (Arbetsmiljöverket)
TWA = Genomsnittligt värde per tidsenhet är baserat på en exponering på 8 tim/dag, 40 tim/vecka

Avsnitt 9: Fysikaliska och kemiska egenskaper

9.1 Information om fysikaliska och kemiska egenskaper

Materialbeskrivning			
Fysisk form	Vätska	Utseende/beskrivning	Reagenserna är klara, färglösa vätskor utan lukt som är primärt buffrade i vattenlösningar.
Färg	Klar	Lukt	Luktlös
Lukttröskel	Data saknas		
Allmänna egenskaper			
Kokpunkt	100 °C (212 °F)	Smältpunkt/fryspunkt	0 °C (32 °F)
Sönderdelningstemperatur	Data saknas	pH	3,5 till 8,8
Specifik vikt/relativ densitet	Data saknas	Löslighet i vatten	Data saknas
Viskositet	Data saknas	Explosiva egenskaper	Data saknas
Oxiderande egenskaper:	Data saknas		
Volatilitet			
Ångtryck	Data saknas	Ångdensitet	Data saknas
Avdunstningshastighet	Data saknas		
Brandfarlighet			
	182,2222 till 293,3333 °C (360 till 560 °F) (Bindande reagens)	Övre exponeringsgräns	Data saknas
Nedre exponeringsgräns	Data saknas	Självantändning	Data saknas
Brandfarlighet (fast, gas)	Data saknas		
Miljö			
Fördelningskoefficient oktanol/vatten	Data saknas		

9.2 Övrig information

Inga ytterligare fysikaliska och kemiska egenskaper noterade.

Avsnitt 10: Stabilitet och reaktivitet

10.1 Reaktivitet

Inga farliga reaktioner kända under normala användningsvillkor.

10.2 Kemisk stabilitet

Stabil

10.3 Risken för farliga reaktioner

Farlig polymerisation uppstår inte.

10.4 Förhållanden som ska undvikas

Oförenliga material. Brinnande plastkassetter som innehåller reagens kan frigöra toxiska biprodukter.

10.5 Oförenliga material

Syror, oxiderande medel.

10.6 Farliga sönderdelningsprodukter

Brinnande plastkassetter som innehåller reagens kan frigöra toxiska biprodukter.

Avsnitt 11: Toxikologisk information

11.1 Information om toxikologiska effekter

Komponenter		
Guanidintiocyanat	593-84-0	**Akut toxicitet:** Intraperitoneal–mus LD50 593 mg/kg

GHS-egenskaper	Klassificering
Akut toxicitet	**EU/CLP**•Data saknas **FN GHS 3**•Akut toxicitet – Oral 5 – ATEmix (oral) = 2 965 mg/kg **OSHA HCS 2012**•Data saknas
Hudfrätning/irritation	**EU/CLP**•Data saknas **FN GHS 3**•Mild hudirritation 3 **OSHA HCS 2012**•Data saknas
Allvarlig ögonskada/irritation	**EU/CLP**•Data saknas **FN GHS 3**•Mild ögonirritation 2B **OSHA HCS 2012**•Mild ögonirritation 2B
Hudsensibilisering	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
Respiratorisk sensibilisering	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
Aspirationsrisk	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
Cancerframkallande egenskaper	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
Könscellsmutagenitet	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
Reproduktionstoxicitet	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
SPECIFIK ORGANTOXICITET-SE	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas
SPECIFIK ORGANTOXICITET-RE	**EU/CLP**•Data saknas **FN GHS 3**•Data saknas **OSHA HCS 2012**•Data saknas

Potentiella hälsoeffekter

Inandning
Akut (omedelbart) Kan orsaka irritation.
Kronisk (försenad) Inga data tillgängliga
Hud
Akut (omedelbart) Orsakar hudirritation.
Kronisk (försenad) Inga data tillgängliga
Ögon
Akut (omedelbart) Orsakar ögonirritation.
Kronisk (försenad) Inga data tillgängliga
Förtäring
Akut (omedelbart) Skadligt vid förtäring.
Kronisk (försenad) Inga data tillgängliga

Nyckeln till förkortningar
LD = Dödlig dos

Avsnitt 12: Ekologisk information

12.1 Toxicitet

LC50 (guppy): 89,1 mg/l vid 96 h

12.2 Motståndskraft och nedbrytbarhet

Materialdata saknas.

12.3 Bioackumuleringsförmåga

Materialdata saknas.

12.4 Rörligheten i jord

Materialdata saknas.

12.5 Resultat av PBT- och vPvB-bedömningen

Ingen PBT- och vPvB-bedömning har gjorts.

12.6 Andra skadliga effekter

Inga studier har hittats.

Avsnitt 13: Avfallshantering

13.1 Metoder för behandling av avfall

Produktavfall	Avyttra innehållet och/eller behållaren i enlighet med lokala, regionala, nationella och/eller internationella förordningar.
Förpackningsavfall	Avyttra innehållet och/eller behållaren i enlighet med lokala, regionala, nationella och/eller internationella förordningar.

13.2 Övriga upplysningar

Biologiska prover, överföringsanordningar och använda kassetter bör anses kunna överföra smittämnen som kräver standardåtgärder. Följ din institutions rutiner för korrekt bortskaffande av använda kassetter och oanvända reagens. Dessa material kan uppvisa egenskaper som kemiskt farligt avfall som kräver specifika nationella eller regionala bortskaffningsförfaranden. Om nationella eller regionala föreskrifter inte ger tydliga riktlinjer för korrekt bortskaffande ska biologiska prover och använda kassetter kasseras enligt WHO:s (Världshälsoorganisationens) föreskrifter om hantering och bortskaffande av avfall.

Avsnitt 14: Transportinformation

	14.1 FN-nummer	14.2 FN lämpligt transportnamn	14.3 Transport riskklass(er)	14.4 Förpackningsgrupp	14.5 Miljöfaror
DOT	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämpligt
TDG	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämpligt
IMO/IMDG	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämpligt
IATA/ICAO	Ej reglerat	Ej reglerat	Ej reglerat	Ej reglerat	Inte tillämpligt

14.6 Särskilda försiktighetsåtgärder för användare

Inga specificerat.

14.7 Bulktransport enligt bilaga II MARPOL 73/78 och IBC-koden

Data saknas.

Avsnitt 15: Gällande föreskrifter

15.1 Säkerhets-, hälso- och miljöföreskrifter/lagstiftning om ämnet eller blandningen

SARA Riskklassificeringar Akut

Förteckning						
Komponent	**CAS**	**Kanada DSL**	**Kanada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Guanidintiocyanat	593-84-0	Ja	Nej	Ja	Nej	Ja

Kanada

Arbete

Kanada – WHMIS – klassificeringar av ämnen

•Guanidintiocyanat	593-84-0	Inte listat

Kanada – WHMIS – lista på angivna ingredienser

•Guanidintiocyanat	593-84-0	Inte listat

Miljö

Kanada – CEPA – lista på prioriterade ämnen

•Guanidintiocyanat	593-84-0	Inte listat

USA

Arbete

USA – OSHA – Processsäkerhetshantering – mycket farliga kemikalier

•Guanidintiocyanat	593-84-0	Inte listat

USA – OSHA – särskilt reglerade kemikalier

•Guanidintiocyanat	593-84-0	Inte listat

Miljö

USA – CAA (Clean Air Act, miljörätt om ren luft) – 1990 farliga luftföroreningar

•Guanidintiocyanat	593-84-0	Inte listat

USA – CERCLA/SARA – farliga ämnen och vilka kvantiteter som bör rapporteras

•Guanidintiocyanat	593-84-0	Inte listat

USA – CERCLA/SARA – radionuklider och de kvantiteter som bör rapporteras

•Guanidintiocyanat	593-84-0	Inte listat

USA – CERCLA/SARA – avsnitt 302 extremt farliga ämnen EPCRA RQs

•Guanidintiocyanat	593-84-0	Inte listat

USA – CERCLA/SARA – avsnitt 302 extremt farliga ämnen TPQs

•Guanidintiocyanat	593-84-0	Inte listat

USA – CERCLA/SARA – avsnitt 313 – utsläppsrapportering

•Guanidintiocyanat	593-84-0	Inte listat

USA – CERCLA/SARA – avsnitt 313 – PBT kemikalielista

•Guanidintiocyanat	593-84-0	Inte listat

USA – Kalifornien

Miljö

USA – Kalifornien – Proposition 65 – lista på cancerframkallande ämnen

•Guanidintiocyanat	593-84-0	Inte listat

USA – Kalifornien – Proposition 65 – utvecklingstoxicitet

•Guanidintiocyanat	593-84-0	Inte listat

USA – Kalifornien – Proposition 65 – högsta tillåtna nivå på dos (MADL)

•Guanidintiocyanat	593-84-0	Inte listat

USA – Kalifornien – Proposition 65 – inga betydande risknivåer (NSRL)

•Guanidintiocyanat	593-84-0	Inte listat

USA – Kalifornien – Proposition 65 – reproduktiv toxicitet – kvinna

•Guanidintiocyanat	593-84-0	Inte listat

USA – Kalifornien – Proposition 65 – reproduktiv toxicitet – man

•Guanidintiocyanat	593-84-0	Inte listat

15.2 Kemikaliesäkerhetsbedömning

Ingen kemikaliesäkerhetsbedömning har genomförts.

Avsnitt 16: Annan information

Relevanta termer (kod och fulltext)

H302 – Skadligt vid förtäring
H313 – Kan vara skadligt vid hudkontakt
H320 – Orsakar ögonirritation

Friskrivningsklausul/ försäkran om ansvar

Ovanstående information är baserad på data tillgängliga för oss och anses vara korrekt. Eftersom informationen kan användas under förhållanden utanför vår kontroll och som är okända för oss, kan vi inte ta något ansvar för resultaten av dess användning och alla personer som tar del av den måste göra en egen bedömning av effekter, egenskaper, skydd, och avyttring som hänför sig till deras särskilda förhållanden. Ingen representation eller garanti, uttrycklig eller underförstådd (inklusive en garanti om lämplighet eller säljbarhet för ett visst ändamål), görs med avseende på material, riktigheten i denna information, de resultat som uppnås vid användning därav, eller de risker som är förknippade med användningen av materialet. Försiktighet skall iakttas vid hantering och användning av materialet. Ovanstående information ges i god tro och med tron att det är korrekt. Från och med dagen för utfärdandet, tillhandahåller vi all relevant information för förutsägbar hantering av materialet. Men i händelse av en skadlig incident i samband med denna produkt, är detta säkerhetsdatablad inte, och är inte avsedd att vara, ett substitut för rådgivning med lämpligt utbildad personal.

Lembar Data Keselamatan
Tanggal Berlaku: Mei, 2020
Menggantikan Tanggal: April 2020

Xpert CT Assay
Xpert CT/NG Assay

Bagian 1: Identifikasi Zat/Campuran dan Perusahaan/Usaha

1.1 Pengidentifikasi Produk

Nama Produk **Xpert CT Assay; Xpert CT/NG Assay**

Kode Produk GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Penggunaan Teridentifikasi yang Relevan atas Zat atau Campuran dan Penggunaan yang Tidak Dianjurkan

Penggunaan Teridentifikasi yang Relevan Penggunaan Laboratorium

1.3 Data Rinci Mengenai Pemasok Lembar Data Keselamatan

Produsen Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Amerika Serikat
www.cepheid.com
AS: techsupport@cepheid.com

Telepon (Umum) 1 (888) 838-3222 - AS Pilihan 2

Telepon (Umum) 1 (408) 541-4191 - Di Luar AS

Pemasok Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Swedia
www.cepheidinternational.com
UE: support@cepheideurope.com

Telepon (Umum) 33 563 825 319 - UE

1.4 Nomor Telepon Darurat

Produsen 1 (800) 535-5053 - INFOTRAC - Darurat 24 jam

Produsen 1 (352) 323-3500 - Di Luar AS

Bagian 2: Identifikasi Bahaya

UE/EEC

Sesuai dengan: Peraturan (EC) No 1272/2008 (CLP)/REACH 1907/2006 [diubah dengan 453/2010]

2.1 Klasifikasi Zat atau Campuran

CLP LDK yang berikut ini untuk produk campuran jadi akhir saja sebagaimana digunakan di laboratorium. Produk berisi manik dan reagensia dalam kartrid atau dalam wadah di luar sistem. Pengecualian untuk pengungkapan beberapa informasi komponen menurut Artikel CLP 1(5)(d) dan 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Tidak dinyatakan

2.2 Elemen Label

CLP

Pernyataan Bahaya	H302 – Berbahaya jika ditelan H313 – Dapat berbahaya jika terkena kulit H320 – Menyebabkan iritasi mata
Pernyataan Kehati-hatian	
Pencegahan	P264 – Cuci dengan saksama setelah penanganan. P270 – Jangan makan, minum, atau merokok ketika menggunakan produk ini.
Respons	P301+312 – JIKA TERTELAN: Hubungi SENTRA INFORMASI KERACUNAN NASIONAL atau dokter segera jika Anda merasa kurang sehat. P330 – Bilas mulut.
Penyimpanan/Pembuangan	P501 – Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.

2.3 Bahaya Lain

CLP	Sesuai dengan Peraturan (EC) No. 1272/2008 (CLP) bahan ini tidak dianggap berbahaya.

GHS PBB Revisi 3 (Pelabelan Isi yang Digunakan pada Produk)

Sesuai dengan: Sistem Harmonisasi Global Klasifikasi dan Pelabelan pada Bahan Kimia (GHS) PBB: Edisi Revisi Ketiga

2.1 Klasifikasi Zat atau Campuran

GHS PBB	Toksisitas Akut Oral 5 Iritasi Kulit Ringan 5 Iritasi Mata Ringan 2B

2.2 Elemen Label

GHS PBB

PERINGATAN

Pernyataan Bahaya	Berbahaya jika ditelan Dapat berbahaya jika terkena kulit Menyebabkan iritasi mata
Pernyataan Kehati-hatian	
Pencegahan	Cuci dengan saksama setelah penanganan.
Respons	Jika terjadi iritasi kulit: Dapatkan saran/bantuan medis. JIKA TERKENA MATA: Bilas dengan hati-hati menggunakan air selama beberapa menit. Lepaskan lensa kontak, jika ada dan mudah dilakukan. Lanjutkan membilas. Jika iritasi mata berlanjut: Dapatkan saran/bantuan medis. Hubungi SENTRA INFORMASI KERACUNAN NASIONAL atau dokter jika Anda merasa kurang sehat.
Penyimpanan/Pembuangan	Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.

2.3 Bahaya Lain

GHS PBB Sesuai dengan Sistem Harmonisasi Global Klasifikasi dan Pelabelan (GHS, Globally Harmonized System), produk ini dianggap berbahaya.

Amerika Serikat (AS)
Sesuai dengan: OSHA 29 CFR 1910.1200 HCS

2.1 Klasifikasi Zat atau Campuran

OSHA HCS 2012 Iritasi Mata Ringan 2B

2.2 Elemen Label

OSHA HCS 2012

Pernyataan Bahaya	Menyebabkan iritasi mata
Pernyataan Kehati-hatian	
Pencegahan	Cuci dengan saksama setelah penanganan.
Respons	JIKA TERKENA MATA: Bilas dengan hati-hati menggunakan air selama beberapa menit. Lepaskan lensa kontak, jika ada dan mudah dilakukan. Lanjutkan membilas. Jika iritasi mata berlanjut: Dapatkan saran/bantuan medis.
Penyimpanan/Pembuangan	Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.

2.3 Bahaya Lain

OSHA HCS 2012 Di bawah Peraturan Amerika Serikat (29 CFR 1910.1200 - Standar Komunikasi Bahaya (Hazard Communication Standard), produk ini tidak dianggap berbahaya.

Kanada
Sesuai dengan: WHMIS

2.1 Klasifikasi Zat atau Campuran

WHMIS Tidak dinyatakan

2.2 Elemen Label

WHMIS Tidak diperlukan elemen label.

2.3 Bahaya Lain

WHMIS Di Kanada, produk yang tercantum di atas tidak dianggap berbahaya menurut Sistem Informasi Bahan Berbahaya di Tempat Kerja (WHMIS [Workplace Hazardous Materials Information System]).

2.4 Informasi Lain

Semua reagensia, manik, dan unsur penyusun lain mempunyai konsentrasi kurang dari 1% dalam campuran dan tidak dianggap berbahaya di bawah peraturan komunikasi bahaya AS (29 CFR 1910.1200), petunjuk UE untuk klasifikasi dan pelabelan zat atau campuran atau Sistem Harmonisasi Global untuk klasifikasi dan pelabelan zat atau campuran.

Bagian 3: Komposisi/Informasi Bahan Penyusun

3.1 Zat

Bahan tidak memenuhi kriteria zat.

3.2 Campuran

Komposisi					
Nama Kimia	**Pengidentifikasi**	**%**	**LD50/LC50**	**Klasifikasi Sesuai dengan Peraturan/Petunjuk**	**Komentar**
Guanidine Tiosianat	**CAS:** 593-84-0 **EINECS:** 209-812-1	10%–20%	593 mg/kg	**CLP UE:** Toks. Akut 5, H302, H313, H320 **GHS PBB:** Toks. Akut 5 (Orl); Irit. Kulit 5; Irit. Mata 2B **OSHA HCS 2012:** Toks. Akut 5 (Orl); Irit. Mata 2B	DTT

Bagian 4: Tindakan Pertolongan Pertama

4.1 Deskripsi Tindakan Pertolongan Pertama pada Kecelakaan

Inhalasi Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Pindahkan korban ke tempat dengan udara segar. Berikan oksigen jika sulit bernapas. Jangan menggunakan metode pernapasan mulut ke mulut jika korban menghirup zat; berikan pernapasan buatan menggunakan masker saku yang dilengkapi katup satu arah atau alat medis pernapasan lain yang sesuai. Berikan pernapasan buatan jika korban tidak bernapas.

Kulit Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Untuk kontak kulit sedikit, jangan menyebarkan bahan pada kulit yang tidak terkena. Jika kulit terkena zat, segera bilas kulit dengan air mengalir selama minimal 20 menit. Lepaskan dan pisahkan pakaian yang terkontaminasi.

Mata Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Jika terkena zat, segera bilas mata dengan air mengalir selama minimal 20 menit. Jika iritasi mata berlanjut: Dapatkan saran/bantuan medis.

Penelanan Pertolongan pertama dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Jika tertelan, bilas mulut dengan air (hanya jika korban dalam keadaan sadar). JANGAN memaksa untuk memuntahkan. Jangan menggunakan metode pernapasan mulut ke mulut jika korban menelan zat. Segera dapatkan bantuan medis jika tertelan.

4.2 Gejala dan Efek Paling Penting, Baik Akut maupun Tertunda

Lihat Bagian 11 - Informasi Toksikologi.

4.3 Indikasi yang Memerlukan Bantuan Medis dan Tindakan Khusus, Jika Diperlukan

Catatan untuk Dokter Semua pengobatan harus didasarkan pada tanda dan gejala penderitaan yang teramati pada pasien. Pertimbangan harus diberikan pada kemungkinan adanya paparan berlebihan terhadap bahan selain produk ini.

Bagian 5: Tindakan Pemadaman Kebakaran

5.1 Media Pemadaman Kebakaran

Media Pemadaman Kebakaran yang Sesuai	KEBAKARAN BESAR: Zat kimia kering, CO2, busa tahan alkohol, semprotan air. KEBAKARAN KECIL: Zat kimia kering, CO2, atau semprotan air.
Media Pemadaman Kebakaran yang Tidak Sesuai	Data tidak tersedia

5.2 Bahaya Khusus yang Timbul dari Zat atau Campuran

Bahaya Kebakaran dan Ledakan yang Tidak Biasa	Kartrid plastik yang berisi reagensia dapat mengeluarkan uap beracun karbon oksida, sulfur oksida, nitrogen oksida.
Produk Pembakaran Berbahaya	Data tidak tersedia

5.3 Saran untuk Petugas Pemadam Kebakaran

Pakaian pelindung petugas pemadam kebakaran struktural memberikan perlindungan terbatas HANYA dalam situasi kebakaran; pakaian tersebut tidak efektif dalam situasi tumpahan saat kontak langsung dengan zat dapat terjadi.
Kenakan pakaian pelindung zat kimia yang direkomendasikan secara spesifik oleh produsen. Pakaian tersebut mungkin menyediakan sedikit perlindungan termal atau tidak sama sekali.
Kenakan alat pernapasan mandiri bertekanan positif (SCBA, Self-Contained Breathing Apparatus).
KEBAKARAN KECIL: Pindahkan wadah dari area kebakaran jika Anda dapat melakukannya tanpa risiko.

Bagian 6: Tindakan Penanggulangan jika terjadi Tumpahan dan Kebocoran

6.1 Langkah Pencegahan Diri, Alat Pelindung, dan Prosedur Tanggap Darurat

Tindakan Pencegahan Diri	Jika kartrid rusak, tindakan pencegahan diri ini berlaku. Kenakan pakaian pelindung yang sesuai. Jangan berjalan melalui bahan yang tertumpah. Jangan menyentuh wadah yang rusak atau bahan yang tertumpah kecuali mengenakan pakaian pelindung yang sesuai. Beri ventilasi pada area yang tertutup.
Prosedur Tanggap Darurat	Prosedur tanggap darurat dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa sesuai rekomendasi.

6.2 Tindakan Pencegahan Lingkungan

Cegah masuknya zat ke dalam saluran air, saluran pembuangan, ruang bawah tanah, atau ruang tertutup.

6.3 Metode dan Bahan untuk Penangkalan dan Pembersihan

Tindakan Membendung/Membersihkan	Untuk tumpahan sedikit, kenakan sarung tangan, dan serap tumpahan dengan handuk kertas. Jangan membuang bahan yang tertumpah ke saluran pembuangan.

6.4 Referensi ke Bagian Lain

Lihat Bagian 8 - Kontrol Paparan/Perlindungan Diri dan Bagian 13 - Pertimbangan Pembuangan/Pemusnahan.

Bagian 7: Penanganan dan Penyimpanan

7.1 Langkah Pencegahan untuk Penanganan yang Aman

Penanganan Tidak diperlukan penanganan khusus. Jika kartrid rusak, hindari kontak dengan reagensia yang tertumpah.

7.2 Kondisi untuk Penyimpanan Aman, Termasuk Inkompatibilitas

Penyimpanan Simpan sesuai dengan label produk. Jauhkan dari bahan yang tidak kompatibel. Simpan di tempat terkunci. Simpan wadah/kemasan dalam keadaan tertutup rapat di tempat yang sejuk dan berventilasi baik.

7.3 Penggunaan Akhir Spesifik

Lihat Bagian 1.2 - Penggunaan teridentifikasi yang relevan.

Bagian 8: Kontrol Paparan/Perlindungan Diri

8.1 Parameter Kontrol

	Batas/Pedoman Paparan			
	Hasil	**ACGIH**	**NIOSH**	**OSHA**
Guanidinium tiosianat	TWA	Tidak ditentukan	Tidak ditentukan	Tidak ditentukan

8.2 Kontrol Paparan

Kontrol/Tindakan Teknik Ventilasi umum yang baik harus digunakan. Tingkat ventilasi harus disesuaikan dengan kondisi. Jika relevan, gunakan penutup proses, ventilasi pembuangan lokal, atau kontrol rekayasa lain untuk menjaga tingkat zat yang terbawa udara berada di bawah batas paparan yang disarankan. Jika batas paparan belum ditentukan, jaga tingkat zat yang terbawa udara pada tingkat yang dapat diterima.

Alat Perlindungan Diri

Pernapasan Alat pernapasan dianggap tidak diperlukan jika bahan digunakan dalam kondisi biasa dan sesuai rekomendasi. Sebaliknya, ikuti peraturan respirator OSHA yang ada di dalam 29 CFR 1910.134 atau Standar Eropa EN 149. Gunakan respirator yang disetujui oleh NIOSH/MSHA atau Standar Eropa EN 149 jika batas paparan terlampaui atau gejala dialami.

Mata/Wajah Kenakan kacamata pengaman untuk cipratan zat kimia.

Kulit/Tubuh Kenakan pakaian pelindung

Kontrol Paparan Lingkungan Ikuti praktik terbaik untuk pengelolaan lokasi dan pembuangan limbah.

Penjelasan singkatan
OSHA = Occupational Safety and Health Administration (Administrasi Kesehatan dan Keselamatan Kerja)
TWA = Time-Weighted Averages, rata-rata terbobot waktu didasarkan pada paparan 8 jam/hari, 40 jam/minggu

Lembar Data Keselamatan
Tanggal Berlaku: Mei, 2020
Menggantikan Tanggal: April 2020

Xpert CT Assay
Xpert CT/NG Assay

Bagian 9: Sifat Fisika dan Kimia

9.1 Informasi tentang Sifat Fisika dan Kimia

Deskripsi Bahan			
Bentuk Fisik	Cairan	Tampilan/Deskripsi	Reagensia adalah cairan bening tanpa warna dan tanpa bau yang terutama berdapar larutan berair.
Warna	Bening	Bau	Tanpa bau
Ambang Bau	Data tidak cukup		
Sifat Umum			
Titik Didih	100 °C (212 °F)	Titik Leleh/Titik Beku	0 °C (32 °F)
Suhu Dekomposisi	Data tidak cukup	pH	3,5 hingga 8,8
Berat Jenis/Densitas Relatif	Data tidak cukup	Kelarutan Air	Data tidak cukup
Kekentalan	Data tidak cukup	Sifat Eksplosif	Data tidak cukup
Sifat Pengoksidasi:	Data tidak cukup		
Volatilitas			
Tekanan Uap	Data tidak cukup	Densitas Uap	Data tidak cukup
Laju Penguapan	Data tidak cukup		
Kemudahan Menyala			
	182,2222 hingga 293,3333 °C (360 hingga 560 °F) (Reagensia pengikat)	UEL	Data tidak cukup
LEL	Data tidak cukup	Swasulut	Data tidak cukup
Kemudahan Menyala (padat, gas)	Data tidak cukup		
Lingkungan			
Koefisien Partisi Oktanol/Air	Data tidak cukup		

9.2 Informasi Lain

Tidak tercatat adanya parameter fisika dan kimia tambahan.

Bagian 10: Stabilitas dan Reaktivitas

10.1 Reaktivitas

Tidak ada reaksi berbahaya yang diketahui di bawah kondisi penggunaan normal.

10.2 Stabilitas Kimia

Stabil

10.3 Kemungkinan Reaksi Berbahaya

Polimerisasi berbahaya tidak akan terjadi.

10.4 Kondisi untuk Dihindari

Bahan yang Tidak Kompatibel. Membakar kartrid plastik berisi reagensia dapat melepaskan produk sampingan beracun.

10.5 Bahan yang Tidak Kompatibel

Asam, agen pengoksidasi.

10.6 Produk Dekomposisi Berbahaya

Membakar kartrid plastik berisi reagensia dapat melepaskan produk sampingan beracun.

Bagian 11: Informasi Toksikologi

11.1 Informasi Efek Toksikologi

Komponen		
Guanidinium tiosianat	593-84-0	**Toksisitas Akut:** Intraperitoneal-Mencit LD50 593 mg/kg

Sifat GHS	Klasifikasi
Toksisitas Akut	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Toksisitas Akut - Oral 5 - ATEmix (oral) = 2965 mg/kg **OSHA HCS 2012**•Data tidak cukup
Korosi/Iritasi Kulit	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Iritasi Kulit Ringan 3 **OSHA HCS 2012**•Data tidak cukup
Kerusakan/Iritasi Mata Serius	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Iritasi Mata Ringan 2B **OSHA HCS 2012**•Iritasi Mata Ringan 2B
Sensitisasi Kulit	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Sensitisasi Pernapasan	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Bahaya Aspirasi	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Karsinogenisitas	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Mutagenisitas Sel Nutfah	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Toksisitas untuk Reproduksi	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Toksisitas Organ Target Spesifik - Paparan Tunggal (STOT-SE, Specific Target Organ Toxicity - Single Exposure)	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup
Toksisitas Organ Target Spesifik - Paparan Berulang (STOT-RE, Specific Target Organ Toxicity - Repeated Exposure)	**UE/CLP**•Data tidak cukup **GHS PBB 3**•Data tidak cukup **OSHA HCS 2012**•Data tidak cukup

Potensi Efek Kesehatan

Inhalasi	
Akut (Segera)	Dapat menyebabkan iritasi.
Kronis (Tertunda)	Data tidak tersedia
Kulit	
Akut (Segera)	Menyebabkan iritasi kulit.
Kronis (Tertunda)	Data tidak tersedia
Mata	
Akut (Segera)	Menyebabkan iritasi mata.
Kronis (Tertunda)	Data tidak tersedia
Penelanan	
Akut (Segera)	Berbahaya jika ditelan.
Kronis (Tertunda)	Data tidak tersedia

Penjelasan singkatan
LD = Lethal Dose (Dosis Mematikan)

Bagian 12: Informasi Ekologis

12.1 Toksisitas

LC50 (guppy): 89,1 mg/l pada 96 jam

12.2 Persistensi dan Keteruraian

Data bahan tidak cukup.

12.3 Potensi Bioakumulatif

Data bahan tidak cukup.

12.4 Mobilitas dalam Tanah

Data bahan tidak cukup.

12.5 Hasil Pengkajian PBT dan vPvB

Belum dilakukan pengkajian PBT dan vPvB.

12.6 Efek Merugikan yang Lain

Belum ada penelitian.

Bagian 13: Pertimbangan Pembuangan

13.1 Metode Penanganan Limbah

Limbah Produk Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.

Limbah Kemasan Buang isi dan/atau wadah sesuai dengan peraturan setempat, regional, nasional, dan/atau internasional.

13.2 Informasi Lain

Spesimen biologis, alat transfer, dan kartrid bekas harus dianggap sebagai mampu menyebarkan agen yang menular yang membutuhkan pencegahan standar. Ikuti prosedur limbah lingkungan institusi Anda untuk pembuangan dengan benar kartrid bekas dan reagensia tidak terpakai. Berbagai bahan ini dapat menunjukkan karakteristik limbah kimia berbahaya yang membutuhkan prosedur pembuangan spesifik nasional atau regional. Jika peraturan negara atau regional tidak menyediakan arahan yang jelas mengenai pembuangan dengan benar, spesimen biologis dan kartrid bekas harus dibuang sesuai pedoman penanganan dan pembuangan limbah medis dari Organisasi Kesehatan Dunia (WHO, World Health Organization).

Bagian 14: Informasi Pengangkutan

	14.1 Nomor PBB	14.2 Nama Pengapalan yang Sesuai Berdasarkan PBB	14.3 Klasifikasi Bahaya Pengangkutan	14.4 Kelompok Pengemasan	14.5 Bahaya Lingkungan
DOT	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku
TDG	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku
IMO/IMDG	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku
IATA/ICAO	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak Diatur	Tidak berlaku

14.6 Tindakan Pencegahan Khusus untuk Pengguna

Tidak ditentukan.

14.7 Pengangkutan dalam Jumlah Besar menurut Lampiran II dari MARPOL 73/78 dan Pedoman IBC

Data tidak cukup.

Bagian 15: Informasi Peraturan

15.1 Peraturan/Undang-Undang Keselamatan, Kesehatan, dan Lingkungan yang Spesifik untuk Zat dan Campuran

Klasifikasi Bahaya SARA Akut

Inventaris						
Komponen	**CAS**	**Kanada DSL**	**Kanada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Guanidinium tiosianat	593-84-0	Ya	Tidak	Ya	Tidak	Ya

Kanada

Tenaga Kerja

Kanada - WHMIS - Klasifikasi Zat

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Kanada - WHMIS - Daftar Pengungkapan Kandungan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Lingkungan

Kanada - CEPA - Daftar Zat Prioritas

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Amerika Serikat

Tenaga Kerja

A.S. - OSHA - Manajemen Keamanan Proses - Zat Kimia Sangat Berbahaya

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - OSHA - Zat Kimia Teregulasi Secara Spesifik

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Lingkungan

A.S. - Undang-Undang Udara Bersih (CAA, Clean Air Act) - 1990 Polutan Udara Berbahaya

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Zat Berbahaya dan Kuantitas yang Dilaporkan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Radionuklida dan Kuantitas yang Dilaporkan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 302 Zat yang Amat Sangat Berbahaya EPCRA RQs

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 302 Zat yang Amat Sangat Berbahaya TPQs

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 313 - Pelaporan Emisi

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - CERCLA/SARA - Bagian 313 - Daftar Zat Kimia PBT

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

Amerika Serikat - California

Lingkungan

A.S. - California - Proposisi 65 - Daftar Karsinogen

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - California - Proposisi 65 - Toksisitas Perkembangan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - California - Proposisi 65 - Tingkat Dosis Maksimum yang Diizinkan (MADL, Maximum Allowable Dose Levels)

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - California - Proposisi 65 - Tingkat Risiko yang Tidak Signifikan (NSRL, No Significant Risk Levels)

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - California - Proposisi 65 - Toksisitas Reproduktif - Perempuan

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

A.S. - California - Proposisi 65 - Toksisitas Reproduktif - Laki-laki

•Guanidinium tiosianat	593-84-0	Tidak Tercantum

15.2 Pengkajian Keamanan Zat Kimia

Belum dilakukan Pengkajian Keamanan Zat Kimia.

Bagian 16: Informasi Lain

Frasa yang Relevan (kode dan teks lengkap)	H302 – Berbahaya jika ditelan H313 – Dapat berbahaya jika terkena kulit H320 – Menyebabkan iritasi mata
Penafian/Pernyataan Liabilitas	Informasi di atas didasarkan pada data yang tersedia bagi kami dan diyakini kebenarannya. Karena informasi tersebut dapat diterapkan dalam kondisi di luar kendali kami dan dengan cara yang asing bagi kami, kami tidak bertanggung jawab atas hasil penggunaannya dan semua orang yang menerimanya harus menentukan sendiri dampak, sifat, perlindungan, dan pembuangan yang sesuai dengan kondisi khususnya. Tidak ada pernyataan, jaminan, atau garansi, secara tegas atau tersirat (termasuk jaminan akan kesesuaian atau kelayakan diperdagangkan untuk tujuan khusus), yang dibuat berhubungan dengan bahan, akurasi informasi ini, hasil yang akan didapatkan dari penggunaannya, atau bahaya yang terkait dengan penggunaan bahan. Kehati-hatian harus digunakan dalam penanganan dan penggunaan bahan. Informasi di atas diberikan dengan iktikad baik dan dengan keyakinan bahwa itu akurat. Pada tanggal penerbitan, kami menyediakan semua informasi yang relevan dengan penanganan bahan yang diketahui sebelumnya. Namun, jika ada kejadian merugikan yang berhubungan dengan produk ini, Lembar Data Keselamatan bukan, dan tidak ditujukan untuk menggantikan konsultasi dengan personel terlatih yang sesuai.

Penjelasan singkatan
DTT = Data tidak tersedia

Karta charakterystyki substancji niebezpiecznej
Data wejścia w życie: Maja, 2020 r.
Zastępuje wersję z: Kwiecień, 2020 r.

Xpert CT Assay
Xpert CT/NG Assay

Sekcja 1: Identyfikacja substancji/mieszaniny i identyfikacja spółki/przedsiębiorstwa

1.1 Identyfikator produktu

Nazwa produktu **Xpert CT Assay; Xpert CT/NG Assay**

Kod produktu GXCT-CE-10, GXCT/NG-10, GXCT/NG-CE-10, GXCT/NG-120, GXCT/NG-CE-120, GXCT/NGX-CE-10, GXCT/NGX-CE-120, GXCT/NG-CN-10, GXCT/NG-CN-120, 900-0840, 900-0854

1.2 Istotne zidentyfikowane zastosowania substancji lub mieszaniny oraz zastosowania odradzane

Istotne zidentyfikowane zastosowania Zastosowania laboratoryjne

1.3 Dane dotyczące dostawcy karty charakterystyki

Producent Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Stany Zjednoczone
www.cepheid.com
USA: techsupport@cepheid.com

Numer telefonu (informacje ogólne) 1(888) 838-3222 — USA, opcja nr 2

Numer telefonu (informacje ogólne) 1 (408) 541-4191 — spoza USA

Dostawca Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Szwecja
www.cepheidinternational.com
UE: support@cepheideurope.com

Numer telefonu (informacje ogólne) +33 563 825 319 — UE

1.4 Numer telefonu alarmowego

Producent 1 (800) 535-5053 — INFOTRAC — sytuacje awaryjne całodobowo

Producent 1 (352) 323-3500 — spoza USA

Sekcja 2: Identyfikacja zagrożeń

UE/EEC

Zgodnie z: Rozporządzenie (WE) nr 1272/2008 (CLP)/REACH 1907/2006 [z późniejszymi zmianami wprowadzonymi przez 453/2010]

2.1 Klasyfikacja substancji lub mieszaniny

CLP Niniejsza karta charakterystyki substancji dotyczy używanego w laboratorium końcowego, gotowego produktu będącego mieszaniną. Ten produkt zawiera kulki i odczynniki w kartridżach albo w pojemnikach poza instrumentem. Zwolnienia z ujawniania informacji na temat niektórych składników zgodnie z art.1(5)(d) i 29 rozporządzenia CLP i 1910.1200(g)(2)(i)(C)(1) i (2) kodeksu CFR.
Nie sklasyfikowano

2.2 Elementy oznakowania

CLP

Zwroty dotyczące zagrożeń	H302 — Działa szkodliwie po połknięciu H313 — Może działać szkodliwie w kontakcie ze skórą H320 — Powoduje podrażnienie oczu
Zwroty wskazujące środki ostrożności	
Zapobieganie	P264 — Dokładnie umyć po użyciu. P270 — Nie jeść, nie pić i nie palić podczas używania produktu.
Odpowiedź	P301+P312 — W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem. P330 — Wypłukać usta.
Przechowywanie/usuwanie	P501 — Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.

2.3 Inne zagrożenia

CLP Ten materiał nie jest uznawany za niebezpieczny zgodnie z Rozporządzeniem (WE) nr 1272/2008 (CLP).

GHS ONZ rewizja 3 (zawartość etykiety używanej na produktach)

Zgodnie z: Globalnie Zharmonizowanym Systemem Klasyfikacji i Oznakowania Chemikaliów (GHS) ONZ: Trzecie wydanie zrewidowane

2.1 Klasyfikacja substancji lub mieszaniny

GHS ONZ Toksyczność ostra, doustnie 5
Łagodne podrażnienie skóry 5
Łagodne podrażnienie oczu 2B

2.2 Elementy oznakowania

GHS ONZ

OSTRZEŻENIE

Zwroty dotyczące zagrożeń	Działa szkodliwie po połknięciu Może działać szkodliwie w kontakcie ze skórą Powoduje podrażnienie oczu
Zwroty wskazujące środki ostrożności	
Zapobieganie	Dokładnie umyć po użyciu.
Odpowiedź	W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza. W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
Przechowywanie/usuwanie	Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.

2.3 Inne zagrożenia

GHS ONZ Ten produkt jest uznawany za niebezpieczny zgodnie z Globalnie Zharmonizowanym Systemem Klasyfikacji i Oznakowania Chemikaliów (GHS) ONZ.

Stany Zjednoczone (USA)
Zgodnie z: OSHA 29 CFR 1910.1200 HCS

2.1 Klasyfikacja substancji lub mieszaniny

OSHA HCS 2012 Łagodne podrażnienie oczu 2B

2.2 Elementy oznakowania

OSHA HCS 2012

Zwroty dotyczące zagrożeń	Powoduje podrażnienie oczu.
Zwroty wskazujące środki ostrożności	
Zapobieganie	Dokładnie umyć po użyciu.
Odpowiedź	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
Przechowywanie/usuwanie	Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.

2.3 Inne zagrożenia

OSHA HCS 2012 Ten produkt nie jest uznawany za niebezpieczny zgodnie z przepisami prawa Stanów Zjednoczonych (29 CFR 1910.1200 — Hazard Communication Standard, Norma dotycząca przekazywania informacji o zagrożeniach).

Kanada
Zgodnie z: WHMIS

2.1 Klasyfikacja substancji lub mieszaniny

WHMIS Nie sklasyfikowano

2.2 Elementy oznakowania

WHMIS Nie są wymagane żadne elementy etykiety.

2.3 Inne zagrożenia

WHMIS W Kanadzie produkt wymieniony powyżej nie jest uznawany za niebezpieczny zgodnie z systemem WHMIS (Workplace Hazardous Materials Information System, system informacji o produktach niebezpiecznych w miejscu pracy).

2.4 Inne informacje

Wszystkie inne odczynniki, kulki oraz inne składniki występują w mieszaninie w stężeniach mniejszych niż 1% lub nie są uznawane za niebezpieczne zgodnie z przepisami USA dotyczącymi przekazywania informacji o zagrożeniach (29 CFR 1910.1200), dyrektywami UE dotyczącymi klasyfikacji i oznakowania substancji lub mieszanin albo Globalnie Zharmonizowanym Systemem klasyfikacji i oznakowania substancji lub mieszanin.

Sekcja 3: Skład i informacje o składnikach

3.1 Substancje

Materiał nie spełnia kryteriów uznania za substancję.

3.2 Mieszaniny

Skład					
Nazwa chemiczna	**Identyfikatory**	**%**	**LD50/LC50**	**Klasyfikacje zgodnie z rozporządzeniem/dyrektywą**	**Komentarze**
Tiocyjanian guanidyny	**CAS:** 593-84-0 **EINECS:** 209-812-1	10%–20%	593 mg/kg	**UE CLP:** Toksyczność ostra 5, H302, H313, H320 **GHS ONZ:**Toksyczność ostra 5 (doustnie); Działanie drażniące na skórę 5; Działanie drażniące na oczy 2B **OSHA HCS 2012:** Toksyczność ostra 5 (doustnie); Działanie drażniące na oczy 2B	BDD

Sekcja 4: Środki pierwszej pomocy

4.1 Opis środków pierwszej pomocy

Wdychanie

Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. Wyprowadzić poszkodowaną osobę na świeże powietrze. W razie problemów z oddychaniem podać tlen. Nie stosować wentylacji metodą usta-usta, jeżeli osoba poszkodowana wdychała substancję. Zastosować sztuczne oddychanie za pomocą maski twarzowej wyposażonej w zawór jednodrożny albo innego odpowiedniego urządzenia medycznego do wentylacji. Jeżeli osoba poszkodowana nie oddycha, zastosować sztuczne oddychanie.

Skóra

Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W przypadku pomniejszego kontaktu ze skórą należy unikać rozprowadzania materiału na inne części skóry. W razie kontaktu z substancją natychmiast przystąpić do płukania skóry pod bieżącą wodą przez co najmniej 20 minut. Należy zdjąć i odizolować zanieczyszczone ubranie.

Oczy

Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W razie kontaktu z substancją natychmiast przystąpić do płukania oczu pod bieżącą wodą przez co najmniej 20 minut. W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Połknięcie

Nie oczekuje się, aby pierwsza pomoc była konieczna, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W razie połknięcia przepłukać usta wodą (wyłącznie jeżeli poszkodowana osoba jest przytomna). NIE wywoływać wymiotów. Jeżeli poszkodowana osoba połknęła substancję, nie wolno stosować wentylacji metodą usta-usta. W razie połknięcia należy natychmiast skorzystać z pomocy lekarza.

4.2 Najważniejsze ostre i opóźnione objawy oraz skutki narażenia

Patrz sekcja 11 — Informacje toksykologiczne.

4.3 Wskazania dotyczące wszelkiej natychmiastowej pomocy lekarskiej i szczególnego postępowania z poszkodowanym

Uwagi dla lekarza

Wdrażane leczenie powinno zależeć od zaobserwowanych objawów występujących u pacjenta. Należy rozważyć możliwość nadmiernego narażenia na materiały inne niż ten produkt.

Sekcja 5: Postępowanie w przypadku pożaru

5.1 Środki gaśnicze

Odpowiednie środki gaśnicze DUŻE POŻARY: Proszek gaśniczy, CO2, piana odporna na działanie alkoholu lub rozpylana woda.
MAŁE POŻARY: Proszek gaśniczy, CO2 lub rozpylana woda.

Niewłaściwe środki gaśnicze Brak dostępnych danych

5.2 Szczególne zagrożenia związane z substancją lub mieszaniną

Szczególne zagrożenia związane z pożarem i wybuchem Plastikowe kartridże zawierające odczynniki mogą emitować toksyczne opary dwutlenku węgla, tlenków siarki, tlenków azotu.

Niebezpieczne produkty spalania Brak dostępnych danych

5.3 Informacje dla straży pożarnej

Strażacka ognioodporna odzież ochronna zapewnia ograniczoną ochronę WYŁĄCZNIE w przypadku walki z pożarem. Jest ona nieskuteczna w przypadku rozlania materiału, gdzie istnieje możliwość bezpośredniego kontaktu z substancją. Należy wówczas założyć odzież chroniącą przed chemikaliami specjalnie zalecaną przez producenta. Taka odzież może zapewniać niewielką ochronę termiczną lub nie zapewniać takiej ochrony.
Należy używać autonomiczne aparaty oddechowe (SCBA).
MAŁE POŻARY: Jeżeli można to zrobić bez ryzyka, należy wynieść pojemniki z obszaru objętego pożarem.

Sekcja 6: Postępowanie w przypadku niezamierzonego uwolnienia do środowiska

6.1 Indywidualne środki ostrożności, sprzęt ochronny i procedury w sytuacjach awaryjnych

Indywidualne środki ostrożności Podane indywidualne środki ostrożności mają zastosowanie w sytuacji uszkodzenia kartridża. Nosić odpowiednią odzież ochronną. Nie wchodzić w rozlany materiał. Nie dotykać uszkodzonych pojemników lub rozlanego materiału bez używania odpowiedniej odzieży ochronnej. Zapewnić wentylację zamkniętych obszarów.

Procedury awaryjne Nie oczekuje się, aby były wymagane jakiekolwiek procedury awaryjne, jeżeli materiał będzie używany w zwykłych warunkach zgodnie z zaleceniami.

6.2 Środki ostrożności w zakresie ochrony środowiska

Zapobiegać odpływowi do dróg wodnych, kanalizacji, piwnic lub zamkniętych obszarów.

6.3 Metody i materiały zapobiegające rozprzestrzenianiu się skażenia i służące do usuwania skażenia

Metody zapobiegające rozprzestrzenianiu się skażenia i służące do usuwania skażenia W przypadku niewielkich wycieków, założyć rękawice i zebrać wyciek ręcznikiem papierowym. Nie wylewać rozlanych materiałów do kanalizacji.

6.4 Odniesienia do innych sekcji

Patrz sekcja 8 — Kontrola narażenia/środki ochrony indywidualnej i sekcja 13 — Postępowanie z odpadami.

Sekcja 7: Postępowanie z substancjami i mieszaninami oraz ich magazynowanie

7.1 Środki ostrożności dotyczące bezpiecznego postępowania

Obchodzenie się z produktem Nie są wymagane specjalne procedury dotyczące postępowania. W razie uszkodzenia kartridża należy unikać kontaktu z rozlanymi odczynnikami.

7.2 Warunki bezpiecznego magazynowania, łącznie z informacjami dotyczącymi wszelkich wzajemnych niezgodności

Magazynowanie Przechowywać zgodnie z informacjami podanymi na etykiecie produktu. Przechowywać z dala od niezgodnych materiałów. Przechowywać pod zamknięciem. Pojemnik/opakowanie przechowywać ściśle zamknięte w chłodnym i dobrze wentylowanym pomieszczeniu.

7.3 Szczególne zastosowanie(-a) końcowe

Patrz podpunkt 1.2 — Istotne zidentyfikowane zastosowania.

Sekcja 8: Kontrola narażenia/środki ochrony indywidualnej

8.1 Parametry dotyczące kontroli

	Wartości graniczne narażenia/wytyczne			
	Wynik	**ACGIH**	**NIOSH**	**OSHA**
Tiocyjanian guanidyny	TWA	Nie ustalono	Nie ustalono	Nie ustalono

8.2 Kontrola narażenia

Techniczne środki kontroli Należy stosować dobrą wentylację ogólną. Natężenie wentylacji należy dostosować do warunków. Jeśli dotyczy, należy stosować odpowiednie osłony procesowe, lokalną wentylację i wyciągi lub też inne środki techniczne, aby utrzymywać poziom substancji lotnych poniżej dopuszczalnych limitów narażenia. Jeżeli nie określono limitów narażenia, należy utrzymywać dopuszczalny poziom substancji lotnych.

Indywidualny sprzęt ochronny

Ochrona dróg oddechowych Nie oczekuje się, aby sprzęt oddechowy był konieczny, jeżeli materiał będzie używany w zwykłych warunkach i zgodnie z zaleceniami. W innym przypadku należy stosować się do wytycznych organizacji OSHA, dotyczących ochrony układu oddechowego zawartych w rozdziale 29 kodeksu CFR 1910.134 lub w Normie Europejskiej EN 149. W razie przekroczenia limitów narażenia lub wystąpienia objawów należy używać odpowiedniego aparatu oddechowego zgodnego z normą NIOSH/MSHA lub Normą Europejską EN 149.

Ochrona oczu lub twarzy Nosić okulary chroniące przed rozpryskiem substancji chemicznych.

Ochrona skóry lub ciała Nosić odzież ochronną

Kontrola narażenia środowiska Przestrzegać stosowanej w ośrodku najlepszej praktyki dotyczącej postępowania z odpadami oraz ich usuwania.

Legenda dotycząca skrótów
OSHA = Occupational Safety and Health Administration (Administracja ds. higieny i bezpieczeństwa pracy)
TWA = Time-Weighted Average, wartość uśredniona czasowo na podstawie narażenia 8h/dobę, 40h/tydzień

Sekcja 9: Właściwości fizyczne i chemiczne

9.1 Informacje dotyczące właściwości fizycznych i chemicznych

Opis materiału			
Postać fizyczna	Ciecz	Wygląd/opis	Odczynniki to przejrzyste, bezbarwne, bezzapachowe płyny głównie buforowane w roztworach wodnych.
Kolor	Przezroczysty	Zapach	Bezwonne
Próg zapachu	Brak danych		
Właściwości ogólne			
Punkt wrzenia	100 °C (212 °F)	Temperatura topnienia/krzepnięcia	0 °C (32 °F)
Temperatura rozkładu	Brak danych	pH	Od 3,5 do 8,8
Ciężar właściwy/Gęstość względna	Brak danych	Rozpuszczalność w wodzie	Brak danych
Lepkość	Brak danych	Właściwości wybuchowe	Brak danych
Właściwości utleniające:	Brak danych		
Lotność			
Prężność pary	Brak danych	Gęstość pary	Brak danych
Współczynnik parowania	Brak danych		
Łatwopalność			
	Od 182,2222 do 293,3333 °C (od 360 do 560 °F) (odczynnik wiążący)	UEL	Brak danych
LEL	Brak danych	Temperatura samozapłonu	Brak danych
Palność (ciało stałe/gaz)	Brak danych		
Środowisko			
Współczynnik podziału: n-oktanol/woda	Brak danych		

9.2 Inne informacje

Nie odnotowano żadnych dodatkowych parametrów fizycznych ani chemicznych.

Sekcja 10: Stabilność i reaktywność

10.1 Reaktywność

W warunkach prawidłowego stosowania brak znanych niebezpiecznych reakcji.

10.2 Stabilność chemiczna

Produkt stabilny

10.3 Możliwość występowania niebezpiecznych reakcji

Nie dochodzi do niebezpiecznej polimeryzacji.

10.4 Warunki, których należy unikać

Materiały niezgodne. Spalające się plastikowe kartridże zawierające odczynniki mogą uwalniać toksyczne produkty uboczne.

10.5 Materiały niezgodne

Kwasy, środki utleniające.

10.6 Niebezpieczne produkty rozkładu

Spalające się plastikowe kartridże zawierające odczynniki mogą uwalniać toksyczne produkty uboczne.

Sekcja 11: Informacje toksykologiczne

11.1 Informacje dotyczące skutków toksykologicznych

Składniki		
Tiocyjanian guanidyny	593-84-0	**Toksyczność ostra:** LD50 (śródotrzewnowo, mysz), 593 mg/kg

Właściwości GHS	Klasyfikacja
Toksyczność ostra	**UE/CLP**•Brak danych **GHS ONZ 3**•Toksyczność ostra — doustnie 5 — ATEmix (doustnie) = 2965 mg/kg **OSHA HCS 2012**•Brak danych
Działanie żrące/drażniące na skórę	**UE/CLP**•Brak danych **GHS ONZ 3**•Łagodne podrażnienie skóry 3 **OSHA HCS 2012**•Brak danych
Poważne uszkodzenie/podrażnienie oczu	**UE/CLP**•Brak danych **GHS ONZ 3**•Łagodne podrażnienie oczu 2B **OSHA HCS 2012**•Łagodne podrażnienie oczu 2B
Uczulenie skóry	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
Uczulenia układu oddechowego	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
Zagrożenie spowodowane aspiracją	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
Rakotwórczość	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
Działanie mutagenne na komórki rozrodcze	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
Działanie toksyczne na rozrodczość	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
STOT-SE	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych
STOT-RE	**UE/CLP**•Brak danych **GHS ONZ 3**•Brak danych **OSHA HCS 2012**•Brak danych

Możliwy wpływ na zdrowie

Wdychanie
Ostre (natychmiastowe) Może powodować podrażnienia.
Przewlekłe (opóźnione) Brak dostępnych danych

Skóra
Ostre (natychmiastowe) Działa drażniąco na skórę.
Przewlekłe (opóźnione) Brak dostępnych danych

Oczy
Ostre (natychmiastowe) Powoduje podrażnienie oczu.
Przewlekłe (opóźnione) Brak dostępnych danych

Połknięcie
Ostre (natychmiastowe) Działa szkodliwie po połknięciu.
Przewlekłe (opóźnione) Brak dostępnych danych

Legenda dotycząca skrótów
LD = Lethal Dose, dawka śmiertelna

Sekcja 12: Informacje ekologiczne

12.1. Toksyczność

LC50 (gupik): 89,1 mg/l przez 96 h

12.2 Trwałość i zdolność do rozkładu

Niedostateczna ilość istotnych danych.

12.3 Zdolność do bioakumulacji

Niedostateczna ilość istotnych danych.

12.4 Mobilność w glebie

Niedostateczna ilość istotnych danych.

12.5 Wyniki oceny właściwości PBT i vPvB

Nie przeprowadzono ocen właściwości PBT i vPvB.

12.6 Inne szkodliwe skutki działania

Nie odnaleziono żadnych badań.

Sekcja 13: Postępowanie z odpadami

13.1 Metody unieszkodliwiania odpadów

Odpady produktu Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.

Odpady opakowań Zawartość/pojemnik usuwać zgodnie z miejscowymi/regionalnymi/krajowymi/międzynarodowymi przepisami.

13.2 Inne informacje

Próbki biologiczne, wyroby do przenoszenia i użyte kartridże należy traktować jako mogące przenosić czynniki zakaźne i wymagające zachowania standardowych środków ostrożności. Należy przestrzegać obowiązujących w placówce procedur dotyczących odpadów środowiskowych w zakresie odpowiedniego usuwania użytych kartridży i nieużytych odczynników. Materiały te mogą wykazywać cechy niebezpiecznych odpadów chemicznych wymagających konkretnych krajowych lub regionalnych procedur utylizacji. Jeśli krajowe lub regionalne przepisy nie regulują kwestii dotyczących odpowiedniego usuwania, wówczas próbki biologiczne i użyte kartridże należy usuwać zgodnie z wytycznymi Światowej Organizacji Zdrowia (World Health Organization, WHO) dotyczącymi obsługi i usuwania odpadów medycznych.

Sekcja 14: Informacje dotyczące transportu

	14.1 Numer UN (numer ONZ)	14.2 Prawidłowa nazwa przewozowa UN	14.3 Klasa(-y) zagrożenia w transporcie	14.4 Grupa opakowaniowa	14.5 Zagrożenia dla środowiska
DOT	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy
TDG	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy
IMO/IMDG	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy
IATA/ICAO	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie podlega przepisom	Nie dotyczy

14.6 Szczególne środki ostrożności dla użytkowników

Brak podanych.

14.7 Transport luzem zgodnie z załącznikiem II do konwencji MARPOL 73/78 i kodeksem IBC

Brak danych.

Sekcja 15: Informacje dotyczące przepisów prawnych

15.1 Przepisy prawne dotyczące bezpieczeństwa, ochrony zdrowia i środowiska specyficzne dla substancji lub mieszaniny

Klasyfikacja zagrożeń SARA Ostre

Wykaz						
Składnik	**CAS**	**Kanada DSL**	**Kanada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Tiocyjanian guanidyny	593-84-0	Tak	Nie	Tak	Nie	Tak

Kanada

Dotyczące pracy

Kanada — WHMIS — Klasyfikacja substancji
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

Kanada — WHMIS — Lista składników podlegających obowiązkowemu ujawnieniu
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

Dotyczące środowiska

Kanada — CEPA — Lista substancji priorytetowych
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

Stany Zjednoczone

Dotyczące pracy

USA — OSHA — Zarządzanie bezpieczeństwem procesów — wysoce niebezpieczna substancja chemiczna
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — OSHA — Substancje chemiczne podlegające konkretnym regulacjom
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

Dotyczące środowiska

USA — CAA (Clean Air Act, Ustawa o Czystym Powietrzu) — 1990 niebezpiecznych substancji zanieczyszczających powietrze
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — CERCLA/SARA — Substancje niebezpieczne oraz ich zgłaszalne ilości
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — CERCLA/SARA — Radionuklidy oraz ich zgłaszalne ilości
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — CERCLA/SARA — Sekcja 302, zgłaszalne ilości niezwykle niebezpiecznych substancji
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — CERCLA/SARA — Sekcja 302, progowe ilości planowe (TPQ) niezwykle niebezpiecznych substancji
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — CERCLA/SARA — Sekcja 313 — Raportowanie emisji
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

USA — CERCLA/SARA — Sekcja 313 — Wykaz chemikaliów PBT
- Tiocyjanian guanidyny 593-84-0 Nie figuruje

Stany Zjednoczone — Kalifornia

Dotyczące środowiska

USA — Kalifornia — Sprawa 65 — Wykaz karcynogenów		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Toksyczność rozwojowa		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Maksymalne dopuszczalne poziomy dawki (MADL)		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Poziomy braku istotnego zagrożenia (NSRL)		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Toksyczność reprodukcyjna — Kobiety		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje
USA — Kalifornia — Sprawa 65 — Toksyczność reprodukcyjna — Mężczyźni		
•Tiocyjanian guanidyny	593-84-0	Nie figuruje

15.2 Ocena bezpieczeństwa chemicznego

Nie przeprowadzono oceny bezpieczeństwa chemicznego.

Sekcja 16: Inne informacje

Stosowne zwroty (numer i pełny tekst)

H302 — Działa szkodliwie po połknięciu
H313 — Może działać szkodliwie w kontakcie ze skórą
H320 — Powoduje podrażnienie oczu

Oświadczenie dotyczące odpowiedzialności

Powyższe informacje bazują na dostępnych dla nas danych i uważamy je za prawidłowe. Ponieważ informacje mogą być stosowane w warunkach poza naszą kontrolą i których możemy nie znać, nie przyjmujemy jakiejkolwiek odpowiedzialności za wyniki ich wykorzystywania, a wszystkie osoby otrzymujące te informacje muszą we własnym zakresie określić działania, właściwości, zabezpieczenia oraz metody usuwania dotyczące konkretnych warunków. Nie udziela się żadnych gwarancji, wyrażonych czy dorozumianych (w tym gwarancji pokupności lub przydatności do określonego celu) w odniesieniu do materiałów, dokładności niniejszych informacji, wyników uzyskanych w toku wykorzystywania ani zagrożeń powiązanych z używaniem tego materiału. Należy zachować ostrożność podczas pracy z materiałem i przy jego używaniu. Powyższe informacje są przekazywane w dobrej wierze i są uznawane za dokładne. Na dzień publikacji przekazujemy wszystkie informacje stosowne do przewidywalnych zastosowań materiału. Jednakże w sytuacji wystąpienia niepożądanego incydentu skojarzonego z produktem niniejsza karta charakterystyki substancji niebezpiecznej nie stanowi zastępstwa dla konsultacji z odpowiednio przeszkolonym personelem.

Legenda dotycząca skrótów
BDD = Brak dostępnych danych

Safety Data Sheet
Effective Date: June, 2020
Supersedes Date: January, 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifier

Product Name	**Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**
Product Code	SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Relevant Identified Use(s)	Laboratory use

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US: techsupport@cepheid.com
Telephone (General)	1 (888) 838-3222 - US Option 2
Telephone (General)	1 (408) 541-4191 - Outside of the US
Supplier	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden www.cepheidinternational.com EU: support@cepheideurope.com
Telephone (General)	33 563 825 319 - EU
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
Telephone (Australia)	1800 107 884

1.4 Emergency Telephone Number

Manufacturer	1 (800) 535-5053 - INFOTRAC - 24 hr Emergency
Manufacturer	1 (352) 323-3500 - Outside of the US

Section 2: Hazards Identification

EU/EEC

According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the Substance or Mixture

CLP

The following SDS is for the final finished mixture product only as used in the laboratory. The product contains liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

CLP

Hazard Statements No label element(s) required

2.3 Other Hazards

CLP

According to Regulation (EC) No. 1272/2008 (CLP) this material is not considered hazardous.

UN GHS Revision 3

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

2.1 Classification of the Substance or Mixture

UN GHS

The following SDS is for the final finished mixture product only as used in the laboratory. The product contains liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

UN GHS

Hazard Statements No label element(s) required

Precautionary Statements

2.3 Other Hazards

UN GHS

According to the Globally Harmonized System for Classification and Labeling (GHS) this product is not considered hazardous.

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the Substance or Mixture

OSHA HCS 2012

The following SDS is for the final finished mixture product only as used in the laboratory. The product contains liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

OSHA HCS 2012

Hazard Statements No label element(s) required

2.3 Other Hazards

OSHA HCS 2012

This product is not considered hazardous under the U.S. OSHA 29 CFR 1910.1200 Hazard Communication Standard.

Canada
According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS

The following SDS is for the final finished mixture product only as used in the laboratory. The product contains liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

WHMIS

No label element(s) required.

2.3 Other Hazards

WHMIS

In Canada, the product mentioned above is not considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).

2.4 Other Information

Dye constituents are at concentrations less than 1% of the entire article or not regulated as hazardous under US hazard communication regulations (29 CFR 1910.1200), EU Directives for classification and labeling of substances and mixtures, or the Global Harmonization System for classification and labeling of substances or mixtures.

Section 3: Composition/Information on Ingredients

3.1 Substances

Ingredients are not considered hazardous under EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

3.2 Mixtures

Material does not meet the criteria of a mixture.

Section 4: First Aid Measures

4.1 Description of First Aid Measures

Inhalation	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move victim to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing.
Skin	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. For minor skin contact, avoid spreading material on unaffected skin. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Remove and isolate contaminated clothing.
Eye	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.
Ingestion	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Obtain medical attention immediately if ingested.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Refer to Section 11 - Toxicological Information.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician	All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	In case of fire use media as appropriate for surrounding fire.
Unsuitable Extinguishing Media	No data available

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	Not flammable or combustible.
Hazardous Combustion Products	No data available

5.3 Advice for Firefighters

Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.
Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.
Wear positive pressure self-contained breathing apparatus (SCBA).
SMALL FIRES: Move containers from fire area if you can do it without risk.

Section 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions	In the event a cartridge is broken these personal precautions are applicable. Ventilate enclosed areas. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Emergency Procedures	No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Avoid run off to waterways and sewers.

6.3 Methods and Material for Containment and Cleaning Up

Containment/ Clean-up Measures	For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.

6.4 Reference to Other Sections

Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7: Handling and Storage

7.1 Precautions for Safe Handling

Handling	No special handling necessary. If cartridge is broken avoid contact with spilled reagents. Avoid contact with skin and eyes.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Storage	Store according to product labeling. Keep container/package tightly closed in a cool, well-ventilated place. Keep away from incompatible materials.

7.3 Specific End Use(s)

Refer to Section 1.2 - Relevant identified uses.

Section 8: Exposure Controls/Personal Protection

8.1 Control Parameters

Exposure Limits/Guidelines No applicable exposure limits available for product or components.

8.2 Exposure Controls

Engineering Measures/Controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face Wear chemical splash safety goggles.

Skin/Body In laboratory setting, wear gloves and lab coat at a minimum to minimize skin contact.

Environmental Exposure Controls Follow best practice for site management and disposal of waste.

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Dyes are solutions of varying color, components are odorless.
Color	Varying	Odor	Odorless
Odor Threshold	Data lacking		
General Properties			
Boiling Point	100 °C (212 °F)	Melting Point/Freezing Point	0 °C (32 °F)
Decomposition Temperature	Data lacking	pH	6 to 9
Specific Gravity/Relative Density	Data lacking	Water Solubility	Data lacking
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Data lacking	Vapor Density	Data lacking
Evaporation Rate	Data lacking		
Flammability			
Flash Point	Data lacking	UEL	Data lacking
LEL	Data lacking	Autoignition	Data lacking
Flammability (solid, gas)	Data lacking		
Environmental			
Octanol/Water Partition Coefficient	Data lacking		

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical Stability

Stable

10.3 Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4 Conditions to Avoid

No data available

10.5 Incompatible Materials

No data available

10.6 Hazardous Decomposition Products

No data available

Section 11: Toxicological Information

11.1 Information on Toxicological Effects

GHS Properties	Classification
Acute Toxicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Skin Corrosion/Irritation	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Serious Eye Damage/Irritation	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Skin Sensitization	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Respiratory Sensitization	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Aspiration Hazard	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Carcinogenicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Germ Cell Mutagenicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking

GHS Properties	Classification
Toxicity for Reproduction	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-SE	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-RE	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking

Potential Health Effects

Inhalation
Acute (Immediate) No symptoms expected.
Chronic (Delayed) No data available
Skin
Acute (Immediate) No symptoms expected.
Chronic (Delayed) No data available
Eye
Acute (Immediate) No symptoms expected.
Chronic (Delayed) No data available
Ingestion
Acute (Immediate) No data available
Chronic (Delayed) No data available

Section 12: Ecological Information

12.1 Toxicity

Material data lacking.

12.2 Persistence and Degradability

Material data lacking.

12.3 Bioaccumulative Potential

Material data lacking.

12.4 Mobility in Soil

Material data lacking.

12.5 Results of PBT and vPvB Assessment

No PBT and vPvB assessment has been conducted.

12.6 Other Adverse Effects

No studies have been found.

Section 13: Disposal Considerations

13.1 Waste Treatment Methods

Product Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13.2 Other Information

Biological specimens mixed with beads should be treated as capable of transmitting infectious agents. Consult your institution's environmental waste personnel on proper disposal of used specimens.

Section 14: Transport Information

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Transport Hazard Class(es)	14.4 Packing Group	14.5 Environmental Hazards
DOT	NDA	Not Regulated	NDA	NDA	NDA
TDG	NDA	Not Regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not Regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not Regulated	NDA	NDA	NDA

14.6 Special Precautions for User

None specified.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Data lacking.

Section 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SARA Hazard Classifications None

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16: Other Information

Disclaimer/ Statement of Liability

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections, and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

Key to abbreviations
NDA = No data available

Fiche de données de sécurité
Date d'entrée en vigueur : Juin 2020
Remplace la date : Janvier 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Section 1 : Identification de la substance/du mélange et de la compagnie/entreprise

1.1 Identifiant de produit

Nom du produit	**Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**
Code de produit	SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Utilisations pertinentes identifiées de la substance ou du mélange et utilisations contre-indiquées

Utilisation(s) pertinente(s) identifiée(s)	Utilisation en laboratoire

1.3 Coordonnées du fournisseur de la fiche de données de sécurité (FDS)

Fabricant	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 États-Unis www.cepheid.com États-Unis : techsupport@cepheid.com
Téléphone (général)	1 (888) 838-3222 - États-Unis Choix 2
Téléphone (général)	1 (408) 541-4191 - En dehors des États-Unis
Fournisseur	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Suède www.cepheidinternational.com UE : support@cepheideurope.com
Téléphone (général)	33 563 825 319 - UE
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australie www.cepheidinternational.com ANZ : TechSupportANZ@cepheid.com
Téléphone (Australie)	1800 107 884

1.4 Numéro de téléphone d'urgence

Fabricant	1 (800) 535-5053 - INFOTRAC - Urgences 24 h/24
Fabricant	1 (352) 323-3500 - En dehors des États-Unis

Section 2 : Identification des risques

EU/EEC

Selon : Règlement (CE) N° 1272/2008 (CLP)/REACH 1907/2006 [modifié par le 453/2010]

2.1 Classification de la substance ou mélange

CLP La fiche de données de sécurité (FDS) suivante concerne uniquement le mélange fini final, tel qu'utilisé au laboratoire. Le produit contient des liquides. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

CLP

Mentions de danger Aucune étiquette(s) requise

2.3 Autres dangers

CLP Selon le règlement (CE) N° 1272/2008 (CLP), ce produit n'est pas considéré dangereux.

SGH ONU Révision 3

Selon : ONU - Système général harmonisé de classification et d'étiquetage des produits chimiques (SGH) : Troisième édition révisée

2.1 Classification de la substance ou mélange

SGH ONU La fiche de données de sécurité (FDS) suivante concerne uniquement le mélange fini final, tel qu'utilisé au laboratoire. Le produit contient des liquides. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

SGH ONU

Mentions de danger Aucune étiquette(s) requise

Mises en garde

2.3 Autres dangers

SGH ONU Selon le Système général harmonisé de classification et d'étiquetage (SGH), ce produit n'est pas considéré dangereux.

États-Unis (É.-U.)
Selon : OSHA 29 CFR 1910.1200 HCS

2.1 Classification de la substance ou mélange

OSHA HCS 2012 La fiche de données de sécurité (FDS) suivante concerne uniquement le mélange fini final, tel qu'utilisé au laboratoire. Le produit contient des liquides. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

OSHA HCS 2012

Mentions de danger Aucune étiquette(s) requise

2.3 Autres dangers

OSHA HCS 2012 Ce produit n'est pas considéré dangereux en vertu de la norme Communication des dangers 29 CFR 1910.1200 de l'OSHA aux États-Unis.

Canada
Selon : WHMIS

2.1 Classification de la substance ou mélange

WHMIS La fiche de données de sécurité (FDS) suivante concerne uniquement le mélange fini final, tel qu'utilisé au laboratoire. Le produit contient des liquides. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

WHMIS Aucune étiquette(s) requise.

2.3 Autres dangers

WHMIS Au Canada, le produit mentionné ci-dessus n'est pas considéré dangereux en vertu du Système d'information sur les matières dangereuses utilisées au travail (SIMDUT).

2.4 Autres informations

Les constituants colorants sont à des concentrations inférieures à 1 % de l'ensemble du produit ou ne sont pas réglementés comme dangereux selon la réglementation américaine sur la communication des dangers (29 CFR 1910.1200), selon les directives de l'UE concernant la classification et l'étiquetage des substances et des mélanges, ou selon le système international d'harmonisation pour la classification et l'étiquetage des substances ou des mélanges.

Section 3 : Composition/informations sur les ingrédients

3.1 Substances

Les ingrédients ne sont pas considérés comme dangereux selon les directives de l'UE concernant la classification et l'étiquetage des substances et des mélanges, ou selon le système international d'harmonisation pour la classification et l'étiquetage des substances ou des mélanges.

3.2 Mélanges

La matière ne répond pas aux critères d'un mélange.

Section 4 : Mesures de premier secours

4.1 Description des premiers soins

Inhalation — Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. Déplacer la victime à l'air frais. Administrer de l'oxygène si la respiration est difficile. Ne pas faire de bouche-à-bouche si la victime a inhalé la substance ; pratiquer la respiration artificielle à l'aide d'un masque de poche doté d'une valve unidirectionnelle ou d'un autre dispositif médical respiratoire approprié. Pratiquer la respiration artificielle si la victime ne
respire pas.

Peau — Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact cutané mineur, éviter de répandre la matière sur la peau non affectée. En cas de contact avec la substance, rincer immédiatement la peau à l'eau courante pendant au moins 20 minutes. Retirer et isoler les vêtements contaminés.

Yeux — Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact avec la substance, rincer immédiatement les yeux à l'eau courante pendant au moins
20 minutes. Si l'irritation oculaire persiste : consulter un médecin.

Ingestion — Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas d'ingestion, rincer la bouche avec de l'eau (seulement si la victime est consciente). NE PAS faire vomir. Ne pas faire de bouche-à-bouche si la victime a ingéré la substance. Consulter immédiatement un médecin en cas d'ingestion.

4.2 Symptômes et effets les plus importants, aigus et différés

Voir la section 11 - Information toxicologique.

4.3 Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires

Notes pour le médecin — Tous les traitements doivent être basés sur les signes et symptômes de détresse observés chez le patient. Il faut envisager la possibilité d'une surexposition à d'autres matières que ce produit.

Section 5 : Mesures de lutte contre l'incendie

5.1 Agents extincteurs

Agent extincteur convenable	En cas d'incendie, utiliser le moyen d'extinction approprié au feu environnant.
Agent extincteur inapproprié	Aucune donnée disponible

5.2 Dangers particuliers résultant de la substance ou du mélange

Dangers inhabituels d'incendie et d'explosion	Non inflammable ni combustible.
Produits de combustion dangereux	Aucune donnée disponible

5.3 Conseils aux pompiers

Les vêtements structurels de protection des pompiers fournissent une protection limitée UNIQUEMENT en cas d'incendie ; ils ne sont pas efficaces dans les cas de déversement où le contact direct avec la substance est possible. Porter des vêtements de protection chimique spécifiquement recommandés par le fabricant. Ceux-ci peuvent fournir peu ou pas de protection thermique.
Porter un appareil respiratoire autonome à pression positive (ARA).
INCENDIES MINEURS : enlever les conteneurs de la zone d'incendie si vous pouvez le faire sans risque.

Section 6 : Mesures en cas de fuite accidentelle

6.1 Précautions individuelles, équipement de protection et mesures d'urgence

Précautions individuelles	Dans le cas où une cartouche est percée, ces précautions individuelles s'appliquent. Ventiler les espaces clos. Porter les vêtements de protection appropriés. Ne pas marcher à travers la matière déversée. Ne pas toucher les conteneurs endommagés ou la matière déversée sauf en cas de port de vêtements de protection appropriés.
Mesures d'urgence	Aucune procédure d'urgence ne devrait s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations.

6.2 Précautions environnementales

Éviter les déversements dans les cours d'eau et les égouts.

6.3 Méthodes et matériaux de confinement et de nettoyage

Mesures de confinement/ nettoyage	Pour les petits déversements, porter des gants et absorber la matière déversée avec une serviette en papier. Ne pas jeter la matière déversée dans les égouts.

6.4 Référence à d'autres sections

Voir la section 8 - Contrôles de l'exposition/protection individuelle, ainsi que la section 13 - Considérations de mise au rebut.

Section 7 : Manutention et stockage

7.1 Précautions pour une manutention sans danger

Manutention Aucune manipulation spéciale n'est nécessaire. Si une cartouche est percée, éviter tout contact avec les réactifs déversés. Éviter tout contact avec la peau et les yeux.

7.2 Conditions de sécurité du stockage, y compris toutes incompatibilités

Stockage Stocker conformément à l'étiquetage des produits. Conserver le conteneur/emballage hermétiquement fermé dans un endroit frais et bien aéré. Tenir à l'écart des matières incompatibles.

7.3 Utilisation(s) finale(s) spécifique(s)

Voir la section 1.2 - Utilisations pertinentes identifiées.

Section 8 : Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

Limites d'exposition/Lignes directrices Pas de limites d'exposition applicables disponibles pour le produit ou ses composants.

8.2 Contrôles d'exposition

Mesures/contrôles techniques Une bonne ventilation générale doit être utilisée. Les débits de ventilation doivent être adaptés aux conditions. Le cas échéant, utiliser des enceintes d'isolement, une ventilation aspirante locale ou d'autres moyens techniques pour maintenir les concentrations atmosphériques en dessous des limites d'exposition recommandées. Si les limites d'exposition n'ont pas été établies, maintenir les concentrations atmosphériques à un niveau acceptable.

Équipement de protection individuelle

Respiratoire Suivre les réglementations de l'OSHA relatives aux appareils respiratoires définies dans 29 CFR 1910.134 ou la norme européenne EN 149. Utiliser un appareil respiratoire approuvé par le NIOSH/MSHA ou la norme européenne EN 149 si les limites d'exposition sont dépassées ou des symptômes apparaissent.

Yeux/visage Porter des lunettes anti-éclaboussures contre les produits chimiques.

Peau/corps En environnement de laboratoire, porter au minimum des gants et une blouse de laboratoire afin de minimiser le contact avec la peau.

Contrôle d'exposition lié à la protection de l'environnement Suivre les bonnes pratiques pour la gestion de site et l'élimination des déchets.

Section 9 : Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques

Description de la matière			
Forme physique	Liquide	Apparence/Description	Les colorants sont des solutions de couleur variable, dont les composants sont inodores.
Couleur	Variable	Odeur	Inodore
Seuil d'odeur	Manque de données		
Propriétés générales			
Point d'ébullition	100 °C (212 °F)	Point de fusion/Point de congélation	0 °C (32 °F)
Température de décomposition	Manque de données	pH	6 à 9
Densité spécifique/relative	Manque de données	Solubilité dans l'eau	Manque de données
Viscosité	Manque de données	Propriétés explosives	Manque de données
Propriétés comburantes :	Manque de données		
Volatilité			
Pression de vapeur	Manque de données	Densité de vapeur	Manque de données
Taux d'évaporation	Manque de données		
Inflammabilité			
Point d'éclair	Manque de données	LSE	Manque de données
LIE	Manque de données	Auto-inflammation	Manque de données
Inflammabilité (solide, gaz)	Manque de données		
Environnemental(e)			
Coefficient de partage octanol/eau	Manque de données		

9.2 Autres informations

Aucun paramètre physique ou chimique supplémentaire noté.

Section 10 : Stabilité et réactivité

10.1 Réactivité

Pas de réactions dangereuses connues dans des conditions normales d'utilisation.

10.2 Stabilité chimique

Stable

10.3 Possibilité de réactions dangereuses

Il ne se produira pas de polymérisation dangereuse.

10.4 Situations à éviter

Aucune donnée disponible

10.5 Substances incompatibles

Aucune donnée disponible

10.6 Produits de décomposition dangereux

Aucune donnée disponible

Section 11 : Information toxicologique

11.1 Informations sur les effets toxiques

Propriétés SGH	Classification
Toxicité aiguë	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Corrosion/irritation cutanée	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Lésion/irritation grave des yeux	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Sensibilisation cutanée	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Sensibilisation respiratoire	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Danger d'aspiration	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Cancérogénicité	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Mutagénicité de cellule germinale	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Toxicité pour la reproduction	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-SE	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-RE	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données

Effets éventuels sur la santé

Inhalation	
Aigu (immédiat)	Aucun symptôme attendu.
Chronique (différé)	Aucune donnée disponible
Peau	
Aigu (immédiat)	Aucun symptôme attendu.
Chronique (différé)	Aucune donnée disponible
Yeux	
Aigu (immédiat)	Aucun symptôme attendu.
Chronique (différé)	Aucune donnée disponible
Ingestion	
Aigu (immédiat)	Aucune donnée disponible
Chronique (différé)	Aucune donnée disponible

Section 12 : Information écologique

12.1 Toxicité

Manque de données matérielles.

12.2 Persistance et dégradabilité

Manque de données matérielles.

12.3 Potentiel bioaccumulatif

Manque de données matérielles.

12.4 Mobilité dans le sol

Manque de données matérielles.

12.5 Résultats des évaluations PBT et vPvB

Aucune évaluation PBT ou vPvB n'a été réalisée.

12.6 Autres effets nocifs

Aucune étude n'a été trouvée.

Section 13 : Considérations de mise au rebut

13.1 Méthodes de traitement des déchets

Déchets du produit	Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.
Conditionnement des déchets	Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

13.2 Autres informations

Les échantillons biologiques mélangés avec des billes doivent être traités comme s'ils étaient susceptibles de transmettre des agents infectieux. Consulter le personnel chargé des déchets environnementaux auprès de l'établissement pour les consignes concernant l'élimination correcte des échantillons utilisés.

Section 14 : Informations de transport

	14.1 Numéro ONU	14.2 Nom d'expédition des Nations Unies	14.3 Classe(s) de danger pour le transport	14.4 Groupe d'emballage	14.5 Dangers pour l'environnement
DOT	ADD	Non régulé	ADD	ADD	ADD
TDG	ADD	Non régulé	ADD	ADD	ADD
IMO/IMDG	ADD	Non régulé	ADD	ADD	ADD
IATA/ICAO	ADD	Non régulé	ADD	ADD	ADD

14.6 Précautions spéciales pour l'utilisateur

Rien de précisé.

14.7 Transport en vrac conformément à l'annexe II de la convention MARPOL 73/78 et au code IBC

Manque de données.

Section 15 : Informations réglementaires

15.1 Réglementation relative à la sécurité, la santé et l'environnement/législation spécifique à la substance ou au mélange

Classifications de dangers SARA Néant

15.2 Évaluation de sécurité chimique

Aucune évaluation de sécurité chimique n'a été effectuée.

Section 16 : Autres informations

Déclaration de non-responsabilité

Les informations ci-dessus reposent sur les données dont nous disposons et que nous jugeons correctes. Dans la mesure où ces informations peuvent être utilisées dans des conditions hors de notre contrôle et que nous ne connaissons pas nécessairement, nous n'assumons aucune responsabilité pour les conséquences de leur utilisation et toutes les personnes recevant le produit doivent en déterminer personnellement les effets, les propriétés, ainsi que les mesures de protection et d'élimination nécessaires en rapport avec leurs conditions d'utilisation particulières. Aucune représentation, garantie ou assurance, explicite ou implicite (y compris une garantie d'aptitude ou de qualité marchande pour un but particulier) n'est faite concernant les produits, l'exactitude des informations, les résultats découlant de leur utilisation ou les risques liés à l'utilisation du produit. Il y a lieu de faire preuve de prudence lors de la manipulation et de l'utilisation du produit. Les informations ci-dessus sont fournies en toute bonne foi et avec la conviction qu'elles sont exactes. À la date de publication, nous fournissons toutes les informations pertinentes pour la manipulation prévisible du produit. Cependant, dans l'éventualité d'un incident indésirable associé à l'utilisation de ce produit, cette fiche de données de sécurité ne peut pas (et n'est pas conçue pour) se substituer à l'avis d'un personnel correctement formé.

Clef aux abréviations
ADD = Pas de données disponibles

Sicherheitsdatenblatt
Datum des Inkrafttretens: June 2020
Ersetzt (Datum): Januar 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Abschnitt 1: Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktname	**Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**
Produktcode	SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Relevante identifizierte Verwendungen der Substanz oder Mischung und Verwendungen, von denen abgeraten wird

Relevante identifizierte Verwendung(en)	Laborgebrauch

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Vereinigte Staaten www.cepheid.com USA: techsupport@cepheid.com
	Telefon (Zentrale)	1 (888) 838-3222 - USA, Option 2
	Telefon (Zentrale)	1 (408) 541-4191 - außerhalb der USA
Lieferant		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Schweden www.cepheidinternational.com EU: support@cepheideurope.com
	Telefon (Zentrale)	33 563 825 319 – EU
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australien www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefon (Australien)	1800 107 884

1.4 Notrufnummer

Hersteller	1 (800) 535-5053 - INFOTRAC - 24-Stunden-Notruf
Hersteller	1 (352) 323-3500 - außerhalb der USA

Abschnitt 2: Mögliche Gefahren

EU/EWG
Nach: Verordnung (EG) Nr. 1272/2008 (CLP)/REACH 1907/2006 [geändert durch 453/2010]

2.1 Einstufung des Stoffs oder Gemischs

CLP Das folgende SDS gilt für das Fertiggemisch nur, wenn es im Labor benutzt wird. Das Produkt enthält Flüssigkeiten. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Nicht klassifiziert

2.2 Kennzeichnungselemente

CLP

Gefahrenhinweise Kein(e) Beschriftungselement(e) erforderlich

2.3 Sonstige Gefahren

CLP Nach Verordnung (EG) Nr. 1272/2008 (CLP) gilt dieses Material nicht als gefährlich.

UN GHS Revision 3
Nach: Global harmonisiertes System der Einstufung und Kennzeichnung von Chemikalien (GHS) der UN: Dritte überarbeitete Auflage

2.1 Einstufung des Stoffs oder Gemischs

UN GHS Das folgende SDS gilt für das Fertiggemisch nur, wenn es im Labor benutzt wird. Das Produkt enthält Flüssigkeiten. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Nicht klassifiziert

2.2 Kennzeichnungselemente

UN GHS

Gefahrenhinweise Kein(e) Beschriftungselement(e) erforderlich

Sicherheitshinweise

2.3 Sonstige Gefahren

UN GHS Nach dem global harmonisierten System zur Einstufung und Kennzeichnung (GHS) gilt dieses Produkt nicht als gefährlich.

Vereinigte Staaten (VS)
Nach: OSHA 29 CFR 1910.1200 HCS

2.1 Einstufung des Stoffs oder Gemischs

OSHA HCS 2012 Das folgende SDS gilt für das Fertiggemisch nur, wenn es im Labor benutzt wird. Das Produkt enthält Flüssigkeiten. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Nicht klassifiziert

2.2 Kennzeichnungselemente

OSHA HCS 2012

Gefahrenhinweise Kein(e) Beschriftungselement(e) erforderlich

2.3 Sonstige Gefahren

OSHA HCS 2012 Dieses Produkt gilt nicht als gefährlich nach der USA-Norm für Gefahrenkommunikation der OSHA 29 CFR 1910.1200.

Kanada
Nach: WHMIS

2.1 Einstufung des Stoffs oder Gemischs

WHMIS Das folgende SDS gilt für das Fertiggemisch nur, wenn es im Labor benutzt wird. Das Produkt enthält Flüssigkeiten. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).

Nicht klassifiziert

2.2 Kennzeichnungselemente

WHMIS Kein(e) Beschriftungselement(e) erforderlich.

2.3 Sonstige Gefahren

WHMIS In Kanada ist das oben genannte Produkt nach dem Workplace Hazardous Materials Information System (WHMIS) nicht als gefährlich einzustufen.

2.4 Sonstige Angaben

Bestandteile von Färbemitteln sind in Konzentrationen unter 1% im gesamten Produkt enthalten oder werden nicht als gefährlich eingestuft gemäß den US-Richtlinien für die Gefahrenkommunikation (29 CFR 1910.1200), den EU-Richtlinien für die Einstufung und Etikettierung von Stoffen und Gemischen oder dem global harmonisierten System für die Einstufung und Etikettierung von Stoffen oder Gemischen.

Abschnitt 3: Zusammensetzung/Angaben zu den Bestandteilen

3.1 Stoffe

Die Inhaltsstoffe gelten nach EU-Richtlinien zur Einstufung und Etikettierung von Stoffen oder Gemischen oder dem global harmonisierten System für die Einstufung und Etikettierung von Stoffen oder Gemischen nicht als gefährlich.

3.2 Gemische

Material erfüllt nicht die Kriterien eines Gemischs.

Abschnitt 4: Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Einatmen
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Verunfallten an die frische Luft bringen. Bei Atemschwierigkeiten Sauerstoffzufuhr einleiten. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat; künstliche Beatmung mit einer mit Einwegventil ausgestatteten Taschen-Sauerstoffmaske oder sonstigem geeigneten medizinischen Beatmungsgerät einleiten. Bei Atemstillstand künstliche Beatmung umgehend einleiten.

Haut
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei geringem Hautkontakt Material nicht auf andere Hautbereiche verteilen. Im Falle eines Hautkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Verunreinigte Kleidung entfernen und isolieren.

Augen
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Im Falle eines Augenkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Verschlucken
Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei Einnahme Mund mit Wasser ausspülen (nur, wenn die Person bei Bewusstsein ist). KEIN Erbrechen herbeiführen. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat. Bei Einnahme sofort Arzt zu Rate ziehen.

4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen

Siehe Abschnitt 11 - Toxikologische Angaben.

4.3 Hinweis auf ärztliche Soforthilfe oder Spezialbehandlung

Hinweise für den Arzt
Alle Behandlungsmaßnahmen sollten auf den beobachteten Anzeichen und Symptomen von Erschöpfung beim Patienten basieren. Außerdem ist zu berücksichtigen, dass es möglicherweise zum Kontakt mit anderen Materialien zusätzlich zu diesem Produkt kam.

Abschnitt 5: Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel
Im Brandfall die entsprechenden Löschmittel für den Umgebungsbrand verwenden.

Ungeeignete Löschmittel
Keine Daten verfügbar

5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren

Ungewöhnliche Brand-und Explosionsgefahren
Nicht entflammbar oder brennbar.

Gefährliche Verbrennungsprodukte
Keine Daten verfügbar

5.3 Hinweise für die Brandbekämpfung

Für die Feuerbekämpfung vorgesehene Standardarbeitsschutzbekleidung bietet einen begrenzten Schutz NUR in Brandfällen; sie ist ineffektiv bei Verschüttungen, wo ein direkter Kontakt mit dem Stoff möglich ist.
Chemikalienschutzbekleidung tragen, die speziell vom Hersteller empfohlen wird. Sie kann wenig oder keinen Thermoschutz bieten.
Umgebungsluftunabhängiges Atemschutzgerät (SCBA) für Überdruckbetrieb tragen.
KLEINBRAND: Behälter aus der Brandzone entfernen, wenn es kein Risiko darstellt.

Abschnitt 6: Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Persönliche Schutzmaßnahmen	Wenn eine Kartusche bricht, dann sind diese persönlichen Vorkehrungen anzuwenden. Geschlossene Räume be- oder entlüften. Entsprechende Schutzkleidung tragen. Nicht durch das verschüttete Material hindurch gehen. Beschädigte Behälter oder verschüttetes Material ohne geeignete Schutzkleidung nicht anfassen.
Sofortmaßnahmen	Es sind keine Notfallmaßnahmen erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird.

6.2 Umweltschutzmaßnahmen

Ablauf in Gewässer und Abwasserleitungen vermeiden.

6.3 Methoden und Material für Rückhaltung und Reinigung

Maßnahmen zur Rückhaltung/ Reinigung	Bei kleinen Verschüttungen Handschuhe tragen und Verschüttung mit einem Papiertuch aufnehmen. Verschüttetes Material nicht durch den Abfluss entsorgen.

6.4 Verweis auf andere Abschnitte

Siehe Abschnitt 8 - Einwirkungskontrolle/Personenschutz und Abschnitt 13 - Überlegungen zur Entsorgung.

Abschnitt 7: Handhabung und Lagerung

7.1 Schutzmaßnahmen zur sicheren Handhabung

Handhabung	Keine spezielle Handhabung notwendig. Wenn eine Kartusche gebrochen ist, dann ist der Kontakt mit verschütteten Reagenzien zu vermeiden. Kontakt mit Haut und Augen vermeiden.

7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Umweltverträglichkeiten

Lagerung	Produkt gemäß der Etikettierung lagern. Behälter/Verpackung dicht verschlossen an kühlem, gut belüftetem Ort lagern. Von nicht kompatiblem Material fernhalten.

7.3 Spezifische Endanwendungen

Siehe Abschnitt 1.2 - Relevante identifizierte Nutzung.

Abschnitt 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstung

8.1 Zu überwachende Parameter

Expositionsgrenzwerte/Richtlinien Keine geltenden Grenzwerte verfügbar für Produkte oder Komponenten.

8.2 Begrenzung und Überwachung der Exposition

Technische Maßnahmen/ Kontrollen Es ist eine gute allgemeine Belüftung anzuwenden. Die Belüftungszahl sollte den Bedingungen entsprechen. Prozesskammern, lokale Abzugsanlage oder andere technische Kontrollmittel verwenden, um die Konzentration in der Luft unter den empfohlenen Grenzwerten zu halten. Wenn keine Grenzwerte festgelegt wurden, sind die Konzentrationen auf einem akzeptablen Niveau zu halten.

Persönliche Schutzausrüstung

Atemwege OSHA-Vorgaben für Atemschutzgeräte aus 29 CFR 1910.134 oder der Europäischen Norm EN 149 befolgen. Nach NIOSH/MSHA oder der Europäischen Norm EN 149 zugelassenes Atemschutzgerät benutzen, wenn die Grenzwerte überschritten werden oder Symptome auftreten.

Augen/Gesicht Schutzbrillen gegen Chemikalienspritzer tragen.

Haut/Körper In einer Laborumgebung sind mindestens Handschuhe und ein Laborkittel zu tragen, um den Hautkontakt zu minimieren.

Umweltkontrollmaßnahmen Beste Praktiken bei Bauleitung und Abfallentsorgung anwenden.

Abschnitt 9: Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Materialbeschreibung			
Physische Gestalt	Flüssigkeit	Aussehen/Beschreibung	Färbemittel sind Lösungen in verschiedenen Farben mit geruchlosen Komponenten.
Farbe	Verschieden	Geruch	Geruchlos
Geruchsschwelle	Fehlende Daten		
Allgemeine Eigenschaften			
Siedepunkt	100 °C (212 °F)	Schmelzpunkt/Gefrierpunkt	0 °C (32 °F)
Zersetzungstemperatur	Fehlende Daten	pH	6 bis 9
Spezifisches Gewicht/ Relative Dichte	Fehlende Daten	Wasserlöslichkeit	Fehlende Daten
Viskosität	Fehlende Daten	Explosive Eigenschaften	Fehlende Daten
Oxidationseigenschaften:	Fehlende Daten		
Volatilität			
Dampfdruck	Fehlende Daten	Dampfdichte	Fehlende Daten
Verdunstungsrate	Fehlende Daten		
Entflammbarkeit			
Flammpunkt	Fehlende Daten	Obere Expositionsgrenze	Fehlende Daten
Untere Expositionsgrenze	Fehlende Daten	Selbstzündung	Fehlende Daten
Entflammbarkeit (Feststoff, Gas)	Fehlende Daten		
Umwelt			
Oktanol/Wasser-Verteilungskoeffizient	Fehlende Daten		

9.2 Sonstige Angaben

Keine zusätzlichen physikalischen und chemischen Parameter vermerkt.

Abschnitt 10: Stabilität und Reaktivität

10.1 Reaktivität

Keine gefährliche Reaktion bekannt unter Bedingungen der normalen Verwendung.

10.2 Chemische Stabilität

Stabil

10.3 Möglichkeit gefährlicher Reaktionen

Eine gefährliche Polymerisierung findet nicht statt.

10.4 Zu vermeidende Bedingungen

Keine Daten verfügbar

10.5 Inkompatible Materialien

Keine Daten verfügbar

10.6 Gefährliche Zersetzungsprodukte

Keine Daten verfügbar

Abschnitt 11: Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

GHS-Eigenschaften	Klassifizierung
Akute Toxizität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Hautätzende Wirkung/Reizung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Schwere Augenschäden/Augenreizung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Hautsensibilisierung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Sensibilisierung der Atemwege	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Aspirationsgefahr	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Karzinogenität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Keimzell-Mutagenität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

GHS-Eigenschaften	Klassifizierung
Reproduktionstoxizität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-SE	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-RE	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

Mögliche gesundheitliche Auswirkungen

Einatmen
Akut (sofort) Keine Symptome erwartet.
Chronisch (verzögert) Keine Daten verfügbar

Haut
Akut (sofort) Keine Symptome erwartet.
Chronisch (verzögert) Keine Daten verfügbar

Augen
Akut (sofort) Keine Symptome erwartet.
Chronisch (verzögert) Keine Daten verfügbar

Verschlucken
Akut (sofort) Keine Daten verfügbar
Chronisch (verzögert) Keine Daten verfügbar

Abschnitt 12: Umweltbezogene Angaben

12.1 Toxizität
Materialdaten fehlen.

12.2 Persistenz und Abbaubarkeit
Materialdaten fehlen.

12.3 Bioakkumulationspotenzial
Materialdaten fehlen.

12.4 Mobilität im Boden
Materialdaten fehlen.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung
Es wurde keine PBT- oder vPvB-Bewertung durchgeführt.

12.6 Andere schädliche Wirkungen
Es wurden keine Studien gefunden.

Abschnitt 13: Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Produktabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

Verpackungsabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

13.2 Sonstige Angaben

Bei mit Kügelchen gemischten biologischen Proben ist davon auszugehen, dass sie Infektionserreger übertragen, und sie sind entsprechend zu behandeln. Konsultieren Sie das Personal für umweltgerechte Abfallentsorgung in Ihrer Institution für die ordnungsgemäße Entsorgung gebrauchter Proben.

Abschnitt 14: Angaben zum Transport

	14.1 UN-Nummer	14.2 Korrekte UN-Bezeichnung des Frachtgutes	14.3 Transportgefahrenklasse(n)	14.4 Verpackungsgruppe	14.5 Umweltrisiken
DOT	KDV	Nicht reglementiert	KDV	KDV	KDV
TDG	KDV	Nicht reglementiert	KDV	KDV	KDV
IMO/IMDG	KDV	Nicht reglementiert	KDV	KDV	KDV
IATA/ICAO	KDV	Nicht reglementiert	KDV	KDV	KDV

14.6 Besondere Vorsichtsmaßnahmen für den Verwender

Keine Angaben.

14.7 Massengutbeförderung gemäß Anhang II des MARPOL-Übereinkommens 73/78 und gemäß IBC-Code

Fehlende Daten.

Abschnitt 15: Rechtsvorschriften

15.1 Vorschriften zur Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

SARA - Klassifizierung von Gefahren Keine

15.2 Stoffsicherheitsbeurteilung

Es wurde keine chemische Sicherheitsanalyse durchgeführt.

Abschnitt 16: Sonstige Angaben

Haftungsausschluss/ Haftungshinweis

Die obigen Informationen basieren auf Daten, die uns verfügbar sind und die wir für korrekt halten. Da die Informationen unter Bedingungen angewendet werden können, die außerhalb unserer Kontrolle liegen und mit denen wir möglicherweise nicht vertraut sind, übernehmen wir keine Verantwortung für die Ergebnisse der Nutzung und alle Personen, die sie erhalten, müssen ihre eigenen Festlegungen bezüglich der Wirkungen, Eigenschaften, Schutzmaßnahmen und Entsorgung vornehmen, die zu den jeweiligen Bedingungen gehören. Es wird keine Zusicherung, Gewährleistung oder Garantie, weder in ausdrücklicher noch in implizierter Form (einschließlich einer Garantie für die Eignung oder Handelsüblichkeit), erteilt werden im Hinblick auf die Stoffe, die Genauigkeit dieser Informationen, die Ergebnisse, die aus deren Nutzung resultieren, oder die Gefahren, die mit der Nutzung des Stoffes verbunden sind. Bei der Handhabung und Nutzung des Stoffs ist Vorsicht anzuwenden. Die obigen Informationen wurden nach bestem Wissen angegeben und für akkurat gehalten. Zum Datum der Ausstellung bieten wir alle Informationen, die für die zu erwartende Handhabung des Stoffs relevant sind. Bei einem Vorfall mit diesem Produkt stellt dieses Sicherheitsdatenblatt keinen Ersatz für die Rücksprache mit entsprechend geschultem Personal dar und ist nicht dazu gedacht.

Schlüssel für Abkürzungen
KDV = Keine Daten verfügbar

Scheda dati di sicurezza
Data di decorrenza: Giugno 2020
Sostituisce la versione del: Gennaio 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Sezione 1: Identificazione della sostanza/miscela e dell'azienda/impresa

1.1 Identificatore del prodotto

Nome prodotto	**Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**
Codice prodotto	SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Usi pertinenti identificati della sostanza o della miscela e utilizzi sconsigliati

Usi pertinenti identificati	Uso in laboratorio

1.3 Dettagli del fornitore della scheda dati di sicurezza

Produttore		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Stati Uniti www.cepheid.com USA: techsupport@cepheid.com
	Telefono (generale)	1 (888) 838-3222 - USA Opzione 2
	Telefono (generale)	1 (408) 541-4191 - Fuori dagli USA
Fornitore		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Svezia www.cepheidinternational.com UE: support@cepheideurope.com
	Telefono (generale)	33 563 825 319 – UE
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefono (Australia)	1800 107 884

1.4 Numero telefonico di emergenza

Produttore	1 (800) 535-5053 - INFOTRAC - Numero telefonico di emergenza attivo 24 ore su 24
Produttore	1 (352) 323-3500 - Fuori dagli USA

Sezione 2: Identificazione dei pericoli

UE/CEE

In ottemperanza a: Normativa (CE) n. 1272/2008 (CLP)/REACH 1907/2006 [emendata dalla 453/2010]

2.1 Classificazione della sostanza o della miscela

CLP La seguente SDS è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Questo prodotto contiene liquidi. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classificato

2.2 Elementi dell'etichetta

CLP

Frasi di rischio Non è richiesta alcuna etichetta

2.3 Altri rischi

CLP In base al Regolamento (CE) n. 1272/2008 (CLP), questo materiale non è considerato pericoloso.

UN GHS Revisione 3

In ottemperanza a: Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN Globally Harmonized System of Classification and Labeling of Chemicals, GHS): Revisione della terza edizione

2.1 Classificazione della sostanza o della miscela

UN GHS La seguente SDS è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Questo prodotto contiene liquidi. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classificato

2.2 Elementi dell'etichetta

UN GHS

Frasi di rischio Non è richiesta alcuna etichetta

Frasi di prudenza

2.3 Altri rischi

UN GHS Ai sensi del GHS (Sistema mondiale armonizzato di classificazione ed etichettatura delle sostanze chimiche) il presente prodotto non è considerato pericoloso.

Stati Uniti (USA)
In ottemperanza a: OSHA 29 CFR 1910.1200 HCS

2.1 Classificazione della sostanza o della miscela

OSHA HCS 2012

La seguente SDS è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Questo prodotto contiene liquidi. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classificato

2.2 Elementi dell'etichetta

OSHA HCS 2012

Frasi di rischio Non è richiesta alcuna etichetta

2.3 Altri rischi

OSHA HCS 2012

Ai sensi della normativa sulla comunicazione del pericolo degli USA, OSHA 29 CFR 1910.1200, il presente prodotto non è considerato pericoloso.

Canada
In ottemperanza a: WHMIS

2.1 Classificazione della sostanza o della miscela

WHMIS

La seguente SDS è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Questo prodotto contiene liquidi. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classificato

2.2 Elementi dell'etichetta

WHMIS Non è richiesta alcuna etichetta.

2.3 Altri rischi

WHMIS

In Canada, il prodotto di cui sopra non è considerato pericoloso ai sensi del sistema di informazioni sui materiali pericolosi sul luogo di lavoro (Workplace Hazardous Materials Information System, WHMIS).

2.4 Altre informazioni

I costituenti dei coloranti hanno concentrazioni inferiori all'1% nell'intero articolo o non sono considerati pericolosi per le normative sulla comunicazione del pericolo degli USA (29 CFR 1910.1200), le direttive UE per la classificazione e l'etichettatura delle sostanze e delle miscele o per il Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche e delle miscele.

Sezione 3: Composizione/Informazioni sugli ingredienti

3.1 Sostanze

I componenti non sono considerati pericolosi ai sensi delle direttive UE per la classificazione e l'etichettatura delle sostanze chimiche o delle miscele o ai sensi del Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche e delle miscele.

3.2 Miscele

Il materiale non soddisfa i criteri di classificazione come miscela.

Sezione 4: Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Inalazione
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. Portare la persona colpita all'aria aperta. Somministrare ossigeno se la respirazione è difficile. Non usare il metodo bocca-a-bocca se la vittima ha inalato la sostanza; effettuare la respirazione artificiale con l'ausilio di una mascherina con valvola unidirezionale o altro dispositivo medico adeguato. Se la vittima non respira, effettuare la respirazione artificiale.

Cute
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di limitato contatto con la pelle, evitare la dispersione del materiale sulla pelle non interessata. In caso di contatto con la sostanza, sciacquare immediatamente la pelle con acqua corrente per almeno
20 minuti. Rimuovere e isolare gli indumenti contaminati.

Occhi
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di contatto con la sostanza, sciacquare immediatamente gli occhi con acqua corrente per almeno 20 minuti. Se l'irritazione degli occhi persiste: consultare un medico.

Ingestione
Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di ingestione, sciacquare la bocca con acqua (solamente se l'infortunato è cosciente). NON provocare il vomito. Non usare il metodo bocca-a-bocca se la vittima ha ingerito la sostanza. In caso di ingestione consultare immediatamente un medico.

4.2 Sintomi ed effetti più importanti, acuti e ritardati

Consultare la Sezione 11 - Informazioni tossicologiche.

4.3 Indicazione delle attenzioni mediche immediate e dei trattamenti speciali necessari

Note per il medico
Tutte le cure dovrebbero basarsi sull'osservazione di segni e sintomi di malessere nel paziente. Dovrebbe essere presa in considerazione la possibilità di sovraesposizione a materiali diversi da questo prodotto.

Sezione 5: Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione adeguati	In caso di incendio, usare mezzi idonei per circoscrivere l'incendio.
Mezzi di estinzione non adeguati	Nessun dato disponibile

5.2 Rischi speciali che scaturiscono dalla sostanza o dalla miscela

Rischi di esplosione e incendi inconsueti	Non infiammabile o combustibile.
Prodotti di combustione pericolosi	Nessun dato disponibile

5.3 Consiglio per i vigili del fuoco

Gli indumenti antincendio strutturali forniscono una protezione limitata SOLO in condizioni di incendio; non sono efficaci in condizioni di fuoriuscite in cui è probabile il contatto diretto con la sostanza.
Indossare abbigliamento protettivo contro gli agenti chimici specificatamente raccomandato dal produttore. Potrebbe fornire limitata o nessuna protezione termica.
Indossare un apparato di respirazione autonomo funzionante a pressione positiva (self-contained breathing apparatus, SCBA).
INCENDI DI DIMENSIONI RIDOTTE: spostare i contenitori dall'area colpita dall'incendio se non comporta alcun rischio.

Sezione 6: Misure contro il versamento accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure di emergenza

Precauzioni personali	Nel caso in cui si rompa una cartuccia, è possibile applicare queste precauzioni personali. Ventilare le aree chiuse. Usare indumenti protettivi adatti. Non camminare sul materiale versato. Toccare i contenitori danneggiati o il materiale versato solo dopo aver indossato l'abbigliamento protettivo adeguato.
Procedure di emergenza	Non si prevede la necessità di procedure di emergenza se il materiale viene utilizzato in condizioni normali come raccomandato.

6.2 Precauzioni ambientali

Evitare l'ingresso nei corsi d'acqua e nelle fognature.

6.3 Metodi e materiali per il contenimento e la pulizia

Misure di contenimento/ pulizia	Per piccole fuoriuscite, indossare guanti e assorbire la fuoriuscita con un tovagliolo di carta. Non gettare il materiale fuoriuscito nei tubi di scarico.

6.4 Riferimento ad altre sezioni

Consultare la Sezione 8 - Controlli dell'esposizione/Protezione personale e la Sezione 13 - Considerazioni per lo smaltimento.

Sezione 7: Manipolazione e stoccaggio

7.1 Precauzioni per la manipolazione sicura

Manipolazione Non è necessario nessun trattamento speciale. Nel caso in cui si rompa una cartuccia, evitare il contatto con i reagenti fuoriusciti. Evitare il contatto con gli occhi e con la pelle.

7.2 Condizioni per lo stoccaggio sicuro, incompatibilità eventuali incluse

Stoccaggio Conservare secondo le indicazioni presenti sull'etichetta del prodotto. Conservare il recipiente/contenitore ben chiuso in luogo fresco e ben ventilato. Tenere lontano dai materiali incompatibili.

7.3 Usi finali specifici

Consultare la Sezione 1.2 - Usi pertinenti identificati.

Sezione 8: Controlli di esposizione/Protezione personale

8.1 Parametri di controllo

Limiti di Esposizione/ Linee Guida Non sono disponibili limiti di esposizione applicabili per il prodotto o i suoi componenti.

8.2 Controlli di esposizione

Misure/Controlli tecnici Garantire una ventilazione generale adeguata. I regimi di ventilazione devono essere adeguati alle condizioni. Se applicabile, utilizzare camere di protezione dei processi, impianti di ventilazione locale o altri controlli tecnici per mantenere i livelli di contaminanti aerei al di sotto dei limiti di esposizione raccomandati. Qualora i limiti di esposizione non fossero stati stabiliti, mantenere i contaminanti aerei a un livello accettabile.

Dispositivi di protezione individuale

Respirazione Attenersi alle indicazioni del respiratore OSHA disponibili in 29 CFR 1910.134 o nella norma europea EN 149. In caso di superamento dei limiti di esposizione o manifestazione di sintomi, usare un respiratore approvato da NIOSH/MSHA o dalla norma europea EN 149.

Occhi/Volto Indossare occhiali protettivi per sostanze chimiche.

Pelle/Corpo In ambiente di laboratorio, indossare, quanto meno, guanti e camici da laboratorio per ridurre al minimo il contatto con la pelle.

Controlli dell'esposizione ambientale Seguire le migliori pratiche per la gestione del sito e per lo smaltimento dei rifiuti.

Sezione 9: Proprietà chimico-fisiche

9.1 Informazioni sulle proprietà chimico-fisiche

Descrizione del materiale			
Forma fisica	Liquido	Aspetto/Descrizione	I coloranti sono soluzioni di colore variabile, i cui componenti sono inodori.
Colore	Variabile	Odore	Inodore
Soglia di odore	Dati mancanti		
Proprietà generali			
Punto di ebollizione	100 °C (212 °F)	Punto di fusione/Punto di congelamento	0 °C (32 °F)
Temperatura di decomposizione	Dati mancanti	pH	Da 6 a 9
Gravità specifica/densità relativa	Dati mancanti	Solubilità in acqua	Dati mancanti
Viscosità	Dati mancanti	Proprietà esplosive	Dati mancanti
Proprietà ossidanti:	Dati mancanti		
Volatilità			
Pressione di vapore	Dati mancanti	Densità del vapore	Dati mancanti
Tasso di evaporazione	Dati mancanti		
Infiammabilità			
Punto di infiammabilità	Dati mancanti	UEL	Dati mancanti
LEL	Dati mancanti	Autoaccensione	Dati mancanti
Infiammabilità (solido, gas)	Dati mancanti		
Ambientali			
Coefficiente di ripartizione ottanolo-acqua	Dati mancanti		

9.2 Altre informazioni

Non sono state osservate altre proprietà chimico-fisiche.

Sezione 10: Stabilità e reattività

10.1 Reattività

Nessuna reazione pericolosa nota nelle normali condizioni di utilizzo.

10.2 Stabilità chimica

Stabile

10.3 Possibilità di reazioni pericolose

Non si verificherà polimerizzazione pericolosa.

10.4 Condizioni da evitare

Nessun dato disponibile

10.5 Materiali incompatibili

Nessun dato disponibile

10.6 Prodotti di decomposizione pericolosi

Nessun dato disponibile

Sezione 11: Informazioni tossicologiche

11.1 Informazioni sugli effetti tossicologici

Proprietà GHS	Classificazione
Tossicità acuta	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Corrosione/Irritazione cutanea	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Grave irritazione/danno oculare	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Sensibilizzazione cutanea	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Sensibilizzazione respiratoria	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Pericolo derivante dall'inalazione	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Cancerogenicità	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Mutagenesi delle cellule embrionali	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Tossicità per la riproduzione	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-SE	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-RE	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti

Potenziali effetti sulla salute

Inalazione
Acuto (immediato) Nessun sintomo previsto.
Cronico (ritardato) Nessun dato disponibile
Cute
Acuto (immediato) Nessun sintomo previsto.
Cronico (ritardato) Nessun dato disponibile
Occhi
Acuto (immediato) Nessun sintomo previsto.
Cronico (ritardato) Nessun dato disponibile

Ingestione	
Acuto (immediato)	Nessun dato disponibile
Cronico (ritardato)	Nessun dato disponibile

Sezione 12: Informazioni ecologiche

12.1 Tossicità

Dati materiale mancanti.

12.2 Persistenza e degradabilità

Dati materiale mancanti.

12.3 Potenziale di bioaccumulo

Dati materiale mancanti.

12.4 Mobilità nel suolo

Dati materiale mancanti.

12.5 Risultati della valutazione PBT e vPvB

Non sono state condotte valutazioni PBT e vPvB.

12.6 Altri effetti avversi

Non sono stati trovati studi.

Sezione 13: Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti del prodotto	Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.
Rifiuti di imballaggio	Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

13.2 Altre informazioni

I campioni biologici, miscelati con le sfere devono essere trattati come materiale in grado di trasmettere agenti infettivi. Rivolgersi al personale addetto allo smaltimento dei rifiuti ambientali del proprio istituto per ottenere informazioni utili sul corretto smaltimento dei campioni usati.

Sezione 14: Informazioni sul trasporto

	14.1 Numero ONU	14.2 Nome di spedizione corretto ONU	14.3 Classi di pericolosità per il trasporto	14.4 Gruppo di imballaggio	14.5 Pericoli ambientali
DOT	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD
TDG	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD
IMO/IMDG	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD
IATA/ICAO	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD

14.6 Precauzioni speciali per l'utilizzatore

Nessuna specificata.

14.7 Trasporto alla rinfusa in base all'Allegato II della Convenzione MARPOL 73/78 e al Codice IBC

Dati mancanti.

Sezione 15: Informazioni regolatorie

15.1 Normative/legislazione in materia di ambiente, salute e sicurezza specifiche per la sostanza o la miscela

Classificazioni dei rischi SARA Nessuno

15.2 Valutazione della sicurezza chimica

Non è stata eseguita alcuna valutazione della sicurezza chimica.

Scheda dati di sicurezza
Data di decorrenza: Giugno 2020
Sostituisce la versione del: Gennaio 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Sezione 16: Altre informazioni

Esclusione/Dichiarazione di responsabilità

Le suddette informazioni si basano su dati a nostra disposizione e ritenuti corretti. Poiché le informazioni possono essere applicate in condizioni che vanno oltre il nostro controllo e che potremmo non conoscere bene, non ci assumiamo nessuna responsabilità per i risultati derivanti dall'uso che ne viene fatto, e tutte le persone che ne usufruiranno devono stabilire gli effetti, le proprietà, le protezioni e lo smaltimento riguardanti ogni singola situazione. Nessuna rappresentazione, garanzia o assicurazione, esplicita o implicita (comprese una garanzia di idoneità o commerciabilità per un particolare scopo), viene fatta per quanto riguarda i materiali, la precisione delle informazioni fornite, i risultati ottenibili dall'uso che ne viene fatto, o i pericoli connessi con l'uso del materiale. L'uso e la manipolazione del materiale devono essere eseguiti con attenzione. Le suddette informazioni sono fornite in buona fede e con la convinzione che siano esatte. A partire dalla data di emissione, vengono fornite tutte le informazioni a disposizione relativamente al trattamento prevedibile del materiale. Tuttavia, in caso di un incidente avverso relativo al prodotto, questa Scheda informativa in materia di sicurezza non è, e non intende essere, il surrogato della consultazione con personale opportunamente addestrato.

Legenda delle abbreviazioni
NDD = Nessun dato disponibile

Ficha de datos de seguridad
Fecha de entrada en vigor: Junio de 2020
Sustituye a fecha: Enero de 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Sección 1: Identificación de la sustancia/mezcla y del proyecto/empresa

1.1 Identificador del producto

Nombre del producto **Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**

Código del producto SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Usos identificados de la sustancia o mezcla y usos no recomendados

Usos identificados Uso en laboratorio

1.3 Detalles del proveedor de la ficha de datos de seguridad

Fabricante Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Estados Unidos
www.cepheid.com
EE. UU.: techsupport@cepheid.com

Teléfono (general) 1 (888) 838-3222 - EE. UU. (opción 2)

Teléfono (general) 1 (408) 541-4191 - Fuera de EE. UU.

1.4 Número de teléfono de emergencia

Fabricante 1 (800) 535-5053 - INFOTRAC - Emergencia (24 h)

Fabricante 1 (352) 323-3500 - Fuera de EE. UU.

Sección 2: Identificación de riesgos

UE/CEE

De acuerdo con: Reglamento (CE) Nº 1272/2008 (CLP)/REACH 1907/2006 [modificado por 453/2010]

2.1 Clasificación de la sustancia o mezcla

CLP La siguiente SDS está destinada exclusivamente al uso en laboratorio del producto de la mezcla final acabado. El producto contiene líquidos. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)y(2).
No clasificado

2.2 Elementos de la etiqueta

CLP

Declaraciones de riesgo No se requieren elementos de etiquetado

2.3 Otros riesgos

CLP De acuerdo con el Reglamento (CE) Nº 1272/2008 (CLP), este material no se considera peligroso.

SGA de la ONU, revisión 3

De acuerdo con: Sistema Globalmente Armonizado (SGA) de Clasificación y Etiquetado de Productos Químicos de la ONU: Tercera edición revisada

2.1 Clasificación de la sustancia o mezcla

SGA de la ONU

La siguiente SDS está destinada exclusivamente al uso en laboratorio del producto de la mezcla final acabado. El producto contiene líquidos. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)y(2).
No clasificado

2.2 Elementos de la etiqueta

SGA de la ONU

Declaraciones de riesgo No se requieren elementos de etiquetado

Declaraciones preventivas

2.3 Otros riesgos

SGA de la ONU

De acuerdo con el Sistema Globalmente Armonizado de Clasificación y Etiquetado de Productos Químicos (SGA), este producto no se considera peligroso.

Estados Unidos (EE. UU.)

De acuerdo con: OSHA 29 CFR 1910.1200 HCS

2.1 Clasificación de la sustancia o mezcla

HCS 2012 de la OSHA

La siguiente SDS está destinada exclusivamente al uso en laboratorio del producto de la mezcla final acabado. El producto contiene líquidos. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)y(2).
No clasificado

2.2 Elementos de la etiqueta

HCS 2012 de la OSHA

Declaraciones de riesgo No se requieren elementos de etiquetado

2.3 Otros riesgos

HCS 2012 de la OSHA

Este producto no se considera peligros conforme a la Norma de comunicación de peligros OSHA de EE.UU. (29 CFR 1910.1200).

Canadá

De acuerdo con: WHMIS

2.1 Clasificación de la sustancia o mezcla

WHMIS

La siguiente SDS está destinada exclusivamente al uso en laboratorio del producto de la mezcla final acabado. El producto contiene líquidos. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)y(2).
No clasificado

2.2 Elementos de la etiqueta

WHMIS No se requieren elementos de etiquetado.

2.3 Otros riesgos

WHMIS El producto mencionado no se considera peligroso en Canadá, de acuerdo con el Sistema de Información de Materiales Peligrosos en el Lugar de Trabajo (WHMIS).

2.4 Información adicional

Los constituyentes del colorante presentan concentraciones inferiores al 1 % de todo el artículo o no son considerados peligrosos según los reglamentos de comunicación de riesgos de EE. UU. (29 CFR 1910.1200), las directivas para la clasificación y el etiquetado de sustancias y mezclas de la UE y el Sistema Globalmente Armonizado de clasificación y etiquetado de sustancias y mezclas.

Sección 3: Composición/información de los ingredientes

3.1 Sustancias

Los ingredientes no se consideran peligrosos según las directivas para la clasificación y el etiquetado de sustancias y mezclas de la UE y el Sistema Globalmente Armonizado de clasificación y etiquetado de sustancias y mezclas.

3.2 Mezclas

El material no cumple con los criterios de una mezcla.

Sección 4: Medidas de primeros auxilios

4.1 Descripción de las medidas de primeros auxilios

Inhalación No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Traslade a la persona al aire libre. Si la respiración resulta difícil, administre oxígeno. No utilice el método de boca a boca si la víctima ha inhalado la sustancia; proporcione respiración artificial con la ayuda de una máscara de bolsillo equipada con una válvula de una sola vía u otro dispositivo médico de respiración adecuado. Si la persona no respira, proporcione respiración artificial.

Piel No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Ante un contacto menor con la piel, evite la difusión del material sobre la piel no afectada. Si entra en contacto con la sustancia, enjuague inmediatamente la piel con agua durante al menos 20 minutos. Retire y aísle la ropa contaminada.

Ojo No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Si entra en contacto con la sustancia, enjuague inmediatamente los ojos con agua durante al menos 20 minutos. Si persiste la irritación ocular: Consultar a un médico.

Ingestión No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. En caso de ingestión, enjuague la boca con agua (solo si la persona está consciente). NO provoque el vómito. No utilice el método de boca a boca si la víctima ha ingerido la sustancia. En caso de ingestión, solicite atención médica inmediatamente.

4.2 Síntomas y efectos más importantes, tanto agudos como retardados

Consulte la Sección 11 - Información toxicológica.

4.3 Indicación de cualquier atención médica inmediata y tratamiento especial necesarios

Notas para el médico	Todos los tratamientos deben basarse en señales y síntomas observados en el paciente. Considere si puede haberse producido una sobreexposición a otros materiales distintos de este producto.

Sección 5: Medidas antiincendios

5.1 Medios de extinción

Medios de extinción adecuados	En caso de incendio, utilice los medios según sea adecuado para el incendio circundante.
Medios de extinción inadecuados	No hay datos disponibles

5.2 Riesgos especiales procedentes de la sustancia o mezcla

Riesgos de incendio y explosión inusuales	No inflamable ni combustible.
Productos de combustión peligrosa	No hay datos disponibles

5.3 Consejos para el personal antiincendios

El traje de protección estándar del personal antiincendios proporciona protección limitada EXCLUSIVAMENTE contra el fuego; no resulta efectivo ante vertidos donde es posible el contacto directo con la sustancia.
Utilice un traje de protección química específicamente recomendado por el fabricante. Puede proporcionar poca o ninguna protección térmica.
Utilice un equipo de respiración autónomo (ERA) de presión positiva.
INCENDIOS MENORES: Mueva los contenedores del área del incendio si la operación no conlleva riesgos.

Sección 6: Medidas en caso de liberación accidental

6.1 Precauciones personales, equipamiento protector y procedimientos de emergencia

Precauciones personales	En caso de romperse un cartucho, pueden aplicarse estas precauciones personales. Ventile las áreas cerradas. Utilice un traje de protección adecuado. No camine a través del material vertido. No toque los contenedores dañados ni los materiales vertidos a menos que utilice un traje de protección adecuado.
Procedimientos de emergencia	Se espera que no sea necesario aplicar procedimientos de emergencia si el material se utiliza bajo condiciones normales y del modo recomendado.

6.2 Precauciones medioambientales

No vierta el material en conductos de agua y desagües.

6.3 Métodos y materiales de contención y limpieza

Medidas de contención/ Limpieza	Para vertidos menores, utilice guantes y absorba el vertido con una toalla de papel. No deseche materiales vertidos por el desagüe.

6.4 Referencia a otras secciones

Consulte la Sección 8 - Controles de exposición/protección personal y la Sección 13 - Consideraciones de eliminación.

Sección 7: Manipulación y almacenamiento

7.1 Precauciones para la manipulación segura

Manipulación	No se necesita ninguna manipulación especial. En caso de romperse un cartucho, evite el contacto con los reactivos vertidos. Evite el contacto con la piel y los ojos.

7.2 Condiciones para el almacenamiento seguro, incluidas posibles incompatibilidades

Almacenamiento	Almacénelos de acuerdo con las indicaciones de su etiqueta. Mantenga el contenedor/embalaje bien cerrado en un lugar fresco y ventilado. Mantenga el producto alejado de materiales incompatibles.

7.3 Usos finales específicos

Consulte la Sección 1.2 - Usos identificados relevantes.

Sección 8: Controles de exposición/protección personal

8.1 Parámetros de control

Directrices/límites de exposición	Sin límites de exposición aplicables disponibles para el producto o componentes.

8.2 Controles de exposición

Controles/medidas de ingeniería	Es necesaria una buena ventilación general. La tasa de ventilación debe corresponder a las condiciones. Si es posible, utilice recintos de procesamiento, ventilación local u otros controles de ingeniería para mantener los niveles del aire por debajo de los límites de exposición recomendados. Si los límites de exposición no se han establecido, mantenga los niveles del aire a un nivel aceptable.
Equipo de protección individual	
Respiratorios	Siga los reglamentos para máscaras de la OSHA incluidas en el estándar 29 CFR 1910.134 y en el estándar europeo EN 149. Utilice una máscara aprobada por la NIOSH/MSHA o la norma europea EN 149 si se superan los límites de exposición o se experimentan síntomas.
Ocular/facial	Utilice gafas de protección contra salpicaduras químicas.
Piel/cuerpo	En el laboratorio, utilice guantes y bata para minimizar el contacto con la piel.
Controles de exposición en el medio ambiente	Siga las buenas prácticas para administrar el centro y eliminar residuos.

Sección 9: Propiedades físicas y químicas

9.1 Información sobre las propiedades físicas y químicas

Descripción del material			
Forma física	Líquido	Aspecto/Descripción	Los colorantes son soluciones de distinto color, los componentes son inodoros.
Color	Distintos	Olor	Inodoro
Umbral de olor	Faltan datos		
Propiedades generales			
Punto de ebullición	100 °C (212 °F)	Punto de fusión/punto de congelación	0 °C (32 °F)
Temperatura de descomposición	Faltan datos	pH	6 a 9
Gravedad específica/densidad relativa	Faltan datos	Hidrosolubilidad	Faltan datos
Viscosidad	Faltan datos	Propiedades explosivas	Faltan datos
Propiedades oxidantes:	Faltan datos		
Volatilidad			
Presión del vapor	Faltan datos	Densidad del vapor	Faltan datos
Tasa de evaporación	Faltan datos		
Inflamabilidad			
Punto de inflamación	Faltan datos	UEL	Faltan datos
LEL	Faltan datos	Autoignición	Faltan datos
Inflamabilidad (sólido, gas)	Faltan datos		
Medioambiental			
Coeficiente de reparto octanol/agua	Faltan datos		

9.2 Información adicional

No se han anotado parámetros físicos o químicos adicionales.

Sección 10: Estabilidad y reactividad

10.1 Reactividad

No se conocen reacciones peligrosas bajo condiciones normales de uso.

10.2 Estabilidad del producto químico

Estable

10.3 Posibilidad de reacciones peligrosas

No ocurrirá polimerización peligrosa.

10.4 Condiciones que se deben evitar

No hay datos disponibles

10.5 Materiales incompatibles

No hay datos disponibles

10.6 Productos de descomposición peligrosos

No hay datos disponibles

Sección 11: Información toxicológica

11.1 Información sobre efectos toxicológicos

Propiedades del SGA	Clasificación
Toxicidad aguda	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Corrosión/irritación cutánea	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Daño/irritación ocular grave	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Sensibilización cutánea	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Sensibilización respiratoria	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Riesgo de aspiración	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Carcinogenicidad	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Mutagenicidad de células germinales	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Toxicidad para la reproducción	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-SE	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-RE	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos

Efectos potenciales en la salud

Inhalación
Agudo (inmediato) No se prevén síntomas.
Crónico (demorado) No hay datos disponibles

Piel
Agudo (inmediato) No se prevén síntomas.
Crónico (demorado) No hay datos disponibles

Ojo
Agudo (inmediato) No se prevén síntomas.
Crónico (demorado) No hay datos disponibles

Ingestión	
Agudo (inmediato)	No hay datos disponibles
Crónico (demorado)	No hay datos disponibles

Sección 12: Información ecológica

12.1 Toxicidad

Faltan datos de material.

12.2 Persistencia y degradabilidad

Faltan datos de material.

12.3 Potencial bioacumulativo

Faltan datos de material.

12.4 Movilidad en suelo

Faltan datos de material.

12.5 Resultados de la evaluación de PBT y mPmB

No se ha realizado ninguna valoración de PBT y mPmB.

12.6 Otros efectos adversos

No se han encontrado estudios.

Sección 13: Consideraciones sobre la eliminación

13.1 Métodos de tratamiento de residuos

Residuos de productos	Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.
Residuos de embalaje	Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

13.2 Información adicional

Las muestras biológicas mezcladas con las microesferas deben tratarse como capaces de transmitir agentes infecciosos. Consultar al personal encargado de los residuos medioambientales del centro cuál es la forma correcta de eliminar las muestras usadas.

Sección 14: Información de transporte

	14.1 Número ONU	14.2 Designación oficial de transporte de la ONU	14.3 Clases de riesgo de transporte	14.4 Grupo de embalaje	14.5 Riesgos para el medioambiente
DOT	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles
TDG	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles
IMO/IMDG	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles
IATA/ICAO	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles

14.6 Precauciones especiales para el usuario

Ninguno especificado.

14.7 Transporte a granel de acuerdo con el Anexo II del MARPOL 73/78 y el código IBC

Faltan datos.

Sección 15: Información reglamentaria

15.1 Legislación/reglamentos de seguridad, salud y medio ambiente específicos para la sustancia o mezcla

Clasificaciones de riesgo de SARA Ninguno

15.2 Evaluación de seguridad del producto químico

No se ha llevado a cabo ninguna evaluación de seguridad química.

Sección 16: Información adicional

Declaración/descargo de responsabilidad

La información anterior está basada en los datos que tenemos y la consideramos correcta. Debido a que la información puede aplicarse bajo condiciones externas a nuestro control y con las que podemos no estar familiarizados, no asumimos ninguna responsabilidad por los resultados de su uso, y todas las personas que la reciban deberán determinar por sí mismas los efectos, propiedades, protecciones y eliminación correspondientes a sus condiciones particulares. No se efectúa ninguna representación ni garantía, expresa o implícita (incluida ninguna garantía de adecuación o comerciabilidad para un objetivo concreto) respecto a los materiales, la precisión de esta información, los resultados obtenidos de su uso ni los riesgos relacionados con dicho uso del material. Tenga precaución al manipular y utilizar el material. La información superior se considera precisa y se ofrece de buena fe. Proporcionamos toda la información relacionada con la manipulación prevista del material en la fecha de publicación. Sin embargo, en caso de ocurrir un incidente adverso asociado a este producto, esta ficha de datos de seguridad no es ni debe utilizarse como sustituto de la consulta con personal formado adecuadamente.

Clave de abreviaturas
NDA = No hay datos disponibles

Ficha de Dados de Segurança
Data de entrada em vigor: Junho de 2020
Data de substituição: Janeiro de 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Secção 1: Identificação da substância/mistura e da empresa/projeto

1.1 Identificador do Produto

Nome do Produto	**Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**
Código do produto	SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Usos relevantes da substância ou mistura identificados, e usos não recomendados

Uso(s) relevante(s) identificado(s)	Utilização laboratorial

1.3 Detalhes do fornecedor da ficha de dados de segurança do material

Fabricante		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Estados Unidos da América www.cepheid.com EUA: techsupport@cepheid.com
	Telefone (Geral)	1 (888) 838-3222 - Opção 2 (EUA)
	Telefone (Geral)	1 (408) 541-4191 - Fora dos EUA
Fornecedor		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Suécia www.cepheidinternational.com UE: support@cepheideurope.com
	Telefone (Geral)	33 563 825 319 - UE
		Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Austrália www.cepheidinternational.com ANZ: TechSupportANZ@cepheid.com
	Telefone (Austrália)	1800 107 884

1.4 Número de telefone de emergência

Fabricante	1 (800) 535-5053 - INFOTRAC - Emergência durante 24 h
Fabricante	1 (352) 323-3500 - Fora dos EUA

Secção 2: Identificação dos riscos

UE/CEE
Segundo: Regulamentação (CE) N.º 1272/2008 (CLP)/REACH 1907/2006 [alterada pela 453/2010]

2.1 Classificação da substância ou mistura

CLP A seguinte ficha de dados de segurança destina-se apenas à mistura do produto final acabado usado em laboratório. O produto contém líquidos. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR.
Não classificado

2.2 Elementos do rótulo

CLP

Declarações de risco Não são necessários elementos do rótulo

2.3 Outros riscos

CLP Este material não é considerado perigoso conforme Regulamentação (CE) N.º 1272/2008 (CLP).

GHS da ONU Revisão 3
Segundo: Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS) da ONU: Terceira edição revista

2.1 Classificação da substância ou mistura

GHS da ONU A seguinte ficha de dados de segurança destina-se apenas à mistura do produto final acabado usado em laboratório. O produto contém líquidos. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR.
Não classificado

2.2 Elementos do rótulo

GHS da ONU

Declarações de risco Não são necessários elementos do rótulo

Declarações de precaução

2.3 Outros riscos

GHS da ONU Este produto não é considerado perigoso de acordo com o Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS).

Estados Unidos da América (EUA)
Segundo: OSHA 29 CFR 1910.1200 HCS

2.1 Classificação da substância ou mistura

OSHA HCS 2012 A seguinte ficha de dados de segurança destina-se apenas à mistura do produto final acabado usado em laboratório. O produto contém líquidos. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR.
Não classificado

2.2 Elementos do rótulo

OSHA HCS 2012

Declarações de risco Não são necessários elementos do rótulo

2.3 Outros riscos

OSHA HCS 2012 Este produto não é considerado perigoso no âmbito da Norma de Comunicação de Perigos, secção 29 1910.1200 do CRF da OSHA dos EUA.

Canadá
Segundo: WHMIS

2.1 Classificação da substância ou mistura

WHMIS A seguinte ficha de dados de segurança destina-se apenas à mistura do produto final acabado usado em laboratório. O produto contém líquidos. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR.
Não classificado

2.2 Elementos do rótulo

WHMIS Não são necessários elementos do rótulo.

2.3 Outros riscos

WHMIS No Canadá, o produto acima referido não é considerado perigoso ao abrigo do Sistema de Informação de Materiais Perigosos no Local de Trabalho (WHMIS).

2.4 Outras informações

Todos os constituintes dos corantes estão em concentrações inferiores a 1% relativas a todo o produto ou não são considerados perigosos ao abrigo das regulamentações de comunicação de perigos (secção 29 1910.1200 do CRF), das diretivas da UE para a classificação e rotulagem de substâncias ou misturas ou do Sistema Mundial Harmonizado para a classificação e rotulagem de substâncias ou misturas.

Secção 3: Composição/informações sobre os ingredientes

3.1 Substâncias

Os componentes não são considerados perigosos ao abrigo das diretivas da UE para a classificação e rotulagem de substâncias ou misturas ou do Sistema Mundial Harmonizado para a classificação e rotulagem de substâncias ou misturas.

3.2 Misturas

O material não satisfaz os critérios de mistura.

Secção 4: Medidas de primeiros socorros

4.1 Descrição das medidas de primeiros socorros

Inalação Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Mover a vítima para o ar livre. Administrar oxigénio se a respiração estiver difícil. Não usar o método boca-a-boca se a vítima tiver inalado a substância; ministre respiração artificial com o auxílio de uma máscara de bolso equipada com uma válvula de 1 via ou outro dispositivo médico de respiração adequado. Administrar respiração artificial se a vítima não estiver a respirar.

Pele Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Para um pequeno contacto com a pele, evitar espalhar o material pela pele não afetada. Em caso de contacto com a substância, lavar imediatamente a pele com água corrente por pelo menos 20 minutos. Despir e isolar a roupa contaminada.

Olhos Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de contacto com a substância, lavar imediatamente os olhos com água corrente por pelo menos 20 minutos. Caso a irritação ocular persista: consulte um médico.

Ingestão Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de ingestão, lavar a boca com água (apenas se a pessoa estiver consciente). NÃO provocar o vómito. Não usar o método boca-a-boca se a vítima tiver ingerido a substância. Em caso de ingestão, consultar um médico imediatamente.

4.2 Sintomas e efeitos mais importantes, tanto agudos quanto retardados

Consultar a Secção 11 - Informação Toxicológica.

4.3 Indicação de qualquer cuidado médico imediato e tratamento especial necessários

Notas para o Médico Todos os tratamentos devem basear-se nos sinais e sintomas de perturbações observados no paciente. Deve ser considerada a possibilidade de sobrexposição a outros materiais além deste produto.

Secção 5: Medidas de combate a incêndios

5.1 Meios de extinção

Meios de extinção adequados Em caso de incêndio, usar os meios apropriados para conter o incêndio.

Meios de extinção inadequados Sem dados disponíveis

5.2 Riscos especiais provocados pela substância ou mistura

Riscos de Incêndios e Explosões Incomuns Não é inflamável nem combustível.

Produtos de combustão de risco Sem dados disponíveis

5.3 Conselhos para bombeiros

Roupas protetoras estruturais de bombeiros fornecem APENAS proteção limitada em caso de incêndio; não são eficientes em situações de derramamentos, onde é possível o contacto direto com a substância.
Usar roupa protetora contra produtos químicos que seja especificamente recomendada pelo fabricante. Poderá fornecer proteção térmica mínima ou nenhuma proteção.
Usar aparelho de respiração autónomo de pressão positiva (SCBA).
PEQUENOS INCÊNDIOS: Se não houver perigos, mover os recipientes da área de incêndio.

Secção 6: Medidas contra Libertação Acidental

6.1 Precauções individuais, equipamento protetor e procedimentos em emergências

Precauções pessoais	No caso de um cartucho se partir, aplicam-se estas precauções de proteção individual. Ventilar áreas fechadas. Usar vestuário de proteção adequado. Não andar sobre material derramado. Não tocar em recipientes danificados ou material derramado a não ser que esteja a usar vestuário de proteção adequado.
Procedimentos de emergência	Não se prevê a necessidade de procedimentos de emergência se o material for usado em condições normais e de acordo com as recomendações.

6.2 Precauções ambientais

Evitar a drenagem para cursos de água e esgotos.

6.3 Métodos e material para contenção e limpeza

Medidas de Contenção/ Limpeza	Em caso de derrames pequenos, usar luvas e absorver o derrame com papel absorvente. Não eliminar os materiais derramados através do sistema de esgotos.

6.4 Referências para outras secções

Consultar a Secção 8 - Controlo da Exposição/Proteção Individual e a Secção 13 - Considerações relativas à eliminação.

Secção 7: Manuseamento e armazenamento

7.1 Precauções para o manuseamento seguro

Manuseamento	Não necessita de manuseamento especial. Se o cartucho se partir, evitar o contacto com os reagentes derramados. Evitar o contacto com a pele e os olhos.

7.2 Condições para armazenamento seguro, incluindo quaisquer incompatibilidades

Armazenamento	Armazenar de acordo com a documentação do produto. Guardar o recipiente/embalagem bem fechado em local fresco e bem ventilado. Manter afastado de materiais incompatíveis.

7.3 Utilização(ões) Final(is) Específica(s)

Consultar a Secção 1.2 - Uso(s) final(is) específico(s)

Secção 8: Controlos e exposição/proteção individual

8.1 Parâmetros de controlo

Limites de Exposição/ Orientações	Não estão disponíveis limites de exposição aplicáveis ao produto nem aos componentes.

8.2 Controlos de exposição

Medidas/Controlos de Engenharia	Deve usar-se uma boa ventilação geral. Os níveis de ventilação devem estar adequados às condições. Se aplicável, usar confinamento de processos, ventilação por exaustão local ou outro controlo técnico para manter os níveis de partículas disseminadas por via aérea em suspensão abaixo dos limites de exposição recomendados. Caso não tenham sido definidos limites, manter os níveis destas partículas em suspensão num nível aceitável.
Equipamento de Proteção Individual	
Respiratório	Seguir as regulamentações da máscara OSHA que se encontram na norma 29 CFR 1910.134 ou na Norma Europeia EN 149. Em caso de ultrapassagem dos limites de exposição ou da ocorrência de sintomas, usar um aparelho de respiração aprovado pelo NIOSH/MSHA ou pela Norma Europeia EN 149.
Olhos/Face	Usar óculos de proteção contra salpicos de produtos químicos.
Pele/Corpo	Em ambiente laboratorial, usar, pelo menos, luvas e bata para minimizar o contacto com a pele.
Controlos Ambientais de Exposição	Seguir as melhores práticas para gestão do local e eliminação dos resíduos.

Secção 9: Propriedades físicas e químicas

9.1 Informações sobre Propriedades Físicas e Químicas

Descrição do material			
Forma física	Líquido	Aspeto/Descrição	Os corantes são soluções de cor variável; os componentes não têm odor.
Cor	Variável	Odor	Inodoro
Limiar do Odor	Dados em falta		
Propriedades gerais			
Ponto de ebulição	100 °C (212 °F)	Ponto de fusão/Ponto de congelamento	0 °C (32 °F)
Temperatura de decomposição	Dados em falta	pH	6 a 9
Gravidade específica/Densidade relativa	Dados em falta	Solubilidade em água	Dados em falta
Viscosidade	Dados em falta	Propriedades explosivas	Dados em falta
Propriedades Oxidantes:	Dados em falta		
Volatilidade			
Pressão do vapor	Dados em falta	Densidade do vapor	Dados em falta
Taxa de evaporação	Dados em falta		
Inflamabilidade			
Ponto de inflamação	Dados em falta	UEL	Dados em falta
LEL	Dados em falta	Autoignição	Dados em falta
Inflamabilidade (sólido/gasoso)	Dados em falta		
Ambiental			
Coeficiente de partição octanol/água	Dados em falta		

9.2 Outras Informações

Não foram observados parâmetros físico-químicos adicionais.

Secção 10: Estabilidade e reatividade

10.1 Reatividade

Desconhecida reação perigosa em condições normais de utilização.

10.2 Estabilidade química

Estável

10.3 Possibilidade de reações perigosas

Não haverá polimerização perigosa.

10.4 Condições a evitar

Sem dados disponíveis

10.5 Materiais incompatíveis

Sem dados disponíveis

10.6 Produtos de decomposição perigosos

Sem dados disponíveis

Secção 11: Informações toxicológicas

11.1 Informações sobre efeitos toxicológicos

Propriedades do GHS	Classificação
Toxicidade aguda	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Corrosão/irritação cutânea	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Lesão/irritação ocular grave	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Sensibilização da pele	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Sensibilização respiratória	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Perigo de aspiração	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Carcinogenicidade	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Mutagenicidade de células germinativas	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta

Propriedades do GHS	Classificação
Toxicidade da reprodução	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-SE	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-RE	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta

Potenciais efeitos na saúde

Inalação
Agudos (imediatos) Não se esperam sintomas.
Crónicos (retardados) Sem dados disponíveis

Pele
Agudos (imediatos) Não se esperam sintomas.
Crónicos (retardados) Sem dados disponíveis

Olhos
Agudos (imediatos) Não se esperam sintomas.
Crónicos (retardados) Sem dados disponíveis

Ingestão
Agudos (imediatos) Sem dados disponíveis
Crónicos (retardados) Sem dados disponíveis

Secção 12: Informações ecológicas

12.1 Toxicidade
Dados dos materiais em falta.

12.2 Persistência e degradabilidade
Dados dos materiais em falta.

12.3 Potencial bioacumulativo
Dados dos materiais em falta.

12.4 Mobilidade no solo
Dados dos materiais em falta.

12.5 Resultados de avaliação PBT e vPvB
Não foi feita a avaliação PBT e vPvB.

12.6 Outros efeitos adversos
Não foram encontrados estudos.

Secção 13: Considerações sobre a eliminação

13.1 Métodos de tratamento de dejetos

Produto residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

Embalagem residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

13.2 Outras informações

As amostras biológicas misturadas com esferas devem ser tratadas como potenciais fontes de transmissão de agentes infeciosos. Consultar os técnicos responsáveis pelos resíduos ambientais da sua instituição relativamente à eliminação correta de amostras usadas.

Secção 14: Informações sobre transporte

	14.1 Número na ONU	14.2 Nome de transporte adequado (ONU)	14.3 Classe(s) de transporte de risco	14.4 Grupo de embalagem	14.5 Perigos ambientais
DOT	NDA	Não regulamentado	NDA	NDA	NDA
TDG	NDA	Não regulamentado	NDA	NDA	NDA
IMO/IMDG	NDA	Não regulamentado	NDA	NDA	NDA
IATA/ICAO	NDA	Não regulamentado	NDA	NDA	NDA

14.6 Precauções especiais para o utilizador

Nenhuma especificada.

14.7 Transporte por volume segundo o Anexo II de MARPOL 73/78 e do Código do IBC

Dados em falta.

Secção 15: Informações regulamentares

15.1 Regulamentos/legislação de segurança, saúde e ambientais, específicos da substância ou mistura

Classificações de Risco SARA Nenhuma

15.2 Avaliação da Segurança Química

Não foi efetuada qualquer Avaliação da Segurança Química.

Secção 16: Outras informações

Renúncia/ Declaração de responsabilidade

A informação supramencionada baseia-se em dados que nos foram disponibilizados e é tida como correta. Dado que a informação pode ser aplicada em condições fora do nosso controlo e com as quais podemos não estar familiarizados, não assumimos qualquer responsabilidade pelo resultado da sua utilização, e todas as pessoas que a recebam têm de determinar individualmente os efeitos, as propriedades, as proteções e os procedimentos de eliminação que se aplicam às suas condições particulares. Não se assume qualquer representação ou garantia, implícita ou explicitamente (incluindo garantia de adequação ou comerciabilidade para uma finalidade específica) em relação aos materiais, à exatidão desta informação, aos resultados obtidos decorrentes da sua utilização ou a perigos relacionados com a utilização deste material. Deve-se ter cuidado no manuseamento e utilização deste material. A informação anterior é disponibilizada de boa-fé e é tida como exata. À data de emissão, fornecemos toda a informação relevante para um manuseamento previsível do material. No entanto, caso ocorra um incidente adverso associado a este produto, esta Ficha de Dados de Segurança não substitui, nem se pretende que substitua, a consulta de um profissional com formação adequada.

Chave para abreviaturas
NDA = Nenhuns Dados Disponíveis

Паспорт безопасности материала
Дата вступления в силу: *июнь 2020 г.*
Отменяет версию документа за: январь 2020 г.

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Раздел 1: Общие сведения о веществе/смеси и производителе

1.1 Идентификатор продукта

Наименование продукта	**Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**
Код продукта	SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 Рекомендованные и не рекомендованные способы применения вещества или смеси

Рекомендованные способы применения	Для использования в лабораторных условиях

1.3 Сведения об организации, предоставившей паспорт безопасности материала

Производитель	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States (США) www.cepheid.com США: techsupport@cepheid.com
Телефон (общий)	1 (888) 838-3222 - США, дополнит. 2
Телефон (общий)	1 (408) 541-4191 - За пределами США
Поставщик	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden (Швеция) www.cepheidinternational.com EC: support@cepheideurope.com
Телефон (общий)	33 563 825 319 - EC
	Cepheid Holdings Pty Ltd 23-27 Chaplin Drive Lane Cove West NSW 2066 Australia (Австралия) www.cepheidinternational.com Австралия и Новая Зеландия: TechSupportANZ@cepheid.com
Телефон (Австралия)	1800 107 884

1.4 Телефон для экстренной связи

Производитель	1 (800) 535-5053 - INFOTRAC - круглосуточный телефон экстренного вызова
Производитель	1 (352) 323-3500 - За пределами США

Паспорт безопасности материала
Дата вступления в силу: *июнь 2020 г.*
Отменяет версию документа за: январь 2020 г.

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Раздел 2: Идентификация опасности

ЕС/ЕЭС

Согласно: Регламенту ЕК (ЕС) № 1272/2008 (CLP)/REACH 1907/2006 [с поправками, внесенными постановлением 453/2010]

2.1 Классификация вещества или смеси

Регламент CLP Следующий паспорт безопасности материала действителен только для готовой смеси, используемой в лабораторных условиях. Этот продукт содержит жидкости. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1) и (2).
Не классифицируется

2.2 Элементы маркировки

Регламент CLP

Указания на опасность Маркировка не требуется.

2.3 Другие факторы опасности

Регламент CLP Согласно Регламенту ЕК № 1272/2008 (CLP) этот материал не считается опасным.

СГС ООН, редакция 3

Согласно: Согласованная на глобальном уровне система классификации опасности и маркировки химической продукции (СГС) ООН: Третья пересмотренная редакция

2.1 Классификация вещества или смеси

СГС ООН Следующий паспорт безопасности материала действителен только для готовой смеси, используемой в лабораторных условиях. Этот продукт содержит жидкости. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1) и (2).
Не классифицируется

2.2 Элементы маркировки

СГС ООН

Указания на опасность Маркировка не требуется.

Меры предосторожности

2.3 Другие факторы опасности

СГС ООН В соответствии с Согласованной на глобальном уровне системой классификации опасности и маркировки химической продукции (СГС) данный продукт не считается опасным.

Паспорт безопасности материала
Дата вступления в силу: *июнь 2020 г.*
Отменяет версию документа за: январь 2020 г.

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

США
Согласно: OSHA 29 CFR 1910.1200 HCS

2.1 Классификация вещества или смеси

OSHA HCS 2012 Следующий паспорт безопасности материала действителен только для готовой смеси, используемой в лабораторных условиях. Этот продукт содержит жидкости. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1) и (2).
Не классифицируется

2.2 Элементы маркировки

OSHA HCS 2012

Указания на опасность Маркировка не требуется.

2.3 Другие факторы опасности

OSHA HCS 2012 Данный продукт не считается опасным согласно стандарту-требованию об оповещении об опасности Управления по охране труда (OSHA) США (документ 29 CFR 1910.1200).

Канада
Согласно: WHMIS

2.1 Классификация вещества или смеси

WHMIS Следующий паспорт безопасности материала действителен только для готовой смеси, используемой в лабораторных условиях. Этот продукт содержит жидкости. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1) и (2).
Не классифицируется

2.2 Элементы маркировки

WHMIS Маркировка не требуется.

2.3 Другие факторы опасности

WHMIS В Канаде указанное выше вещество согласно требованиям Информационной системы по опасным материалам на рабочих местах (WHMIS) не считается опасным.

2.4 Дополнительная информация

Составляющие красителей представлены в концентрации менее 1% от всего продукта или не считаются опасными согласно Стандартам-требованиям США об оповещении об опасности (29 CFR 1910.1200), директивам ЕС в отношении классификации и маркировки веществ и смесей и Согласованной на глобальном уровне системе классификации опасности и маркировки химической продукции.

Раздел 3: Состав/информация о компонентах

3.1 Вещества

Компоненты не считаются опасными согласно директивам ЕС в отношении классификации и маркировке веществ или смесей или по Согласованной на глобальном уровне системе классификации опасности и маркировки химической продукции.

3.2 Смеси

Материал не отвечает критериям классификации, применяемым к смесям.

Раздел 4: Первая медицинская помощь

4.1 Описание мер первой медицинской помощи

Вдыхание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. Вынести пострадавшего на свежий воздух. При затрудненном дыхании дать кислород. При вдыхании вещества не применять искусственное дыхание рот-в-рот. Выполнить искусственное дыхание с помощью карманной маски с клапаном одностороннего действия или другого подходящего медицинского устройства. При остановке дыхания обеспечить искусственное дыхание/ИВЛ.

Кожа Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При незначительном контакте с кожей избегайте распространения материала на незатронутые участки. В случае контакта вещества с кожей незамедлительно промыть пораженный участок проточной водой в течение не менее чем 20 минут. Снять и изолировать загрязненную одежду.

Глаза Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. В случае попадания вещества незамедлительно промыть глаза проточной водой в течение не менее чем 20 минут. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

Проглатывание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При проглатывании прополоскать рот водой (только если человек находится в сознании). НЕ вызывать рвоту. Не применять искусственное дыхание рот-в-рот при проглатывании вещества. При проглатывании материала сразу же обратиться к врачу.

4.2 Наиболее важные симптомы и последствия, проявляющиеся немедленно и с задержкой

См. раздел 11, «Токсикологическая информация».

4.3 Признаки необходимости неотложной медицинской помощи и специального лечения

Примечания для врача Лечение основывать на наблюдаемых симптомах. Учитывать возможность одновременного чрезмерного воздействия на пациента и других веществ, помимо данного продукта.

Раздел 5: Меры противопожарной безопасности

5.1 Средства пожаротушения

Подходящие средства пожаротушения	В случае пожара использовать средства пожаротушения, пригодные для окружающего огня.
Непригодные средства пожаротушения	Данные отсутствуют

5.2 Особые аспекты опасности вещества или смеси

Особая огне- и взрывоопасность	Не огнеопасно и не взрывоопасно.
Опасные продукты горения	Данные отсутствуют

5.3 Рекомендации по пожаротушению

Защитная одежда пожарных для тушения пожаров в зданиях обеспечивает ограниченную защиту ТОЛЬКО в условиях пожара; она не является эффективным средством защиты при разливах с возможным непосредственным контактом с веществами.
Носить одежду для химической защиты, рекомендованную производителем. Она может быть малоэффективна или неэффективна в качестве тепловой защиты.
Использовать автономные дыхательные аппараты, работающие в режиме положительного давления.
НЕБОЛЬШИЕ ПОЖАРЫ. Уберите контейнеры из зоны пожара, если можете сделать это без риска.

Раздел 6: Меры по предотвращению и ликвидации последствий случайного выброса материала

6.1 Меры по обеспечению личной безопасности, средства защиты и действия в чрезвычайной ситуации

Меры по обеспечению личной безопасности	В случае разбития картриджа актуальны указанные меры по обеспечению личной безопасности. Проветрите закрытые помещения. Используйте соответствующую защитную одежду. Не ходите по разлитому/просыпанному материалу. Не прикасайтесь к поврежденным контейнерам или разлитому/просыпанному материалу, если нет соответствующей защитной одежды.
Действия в чрезвычайных ситуациях	Ожидается, что экстренные меры не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций.

6.2 Меры по защите окружающей среды

Не допускать стока в водотоки и системы канализации.

6.3 Методы и средства локализации и очистки

Методы и средства локализации и очистки	При небольших разливах используйте перчатки. Для сбора вещества используйте бумажные полотенца. Не сливать пролитые вещества в канализацию.

6.4 Ссылки на другие разделы

См. раздел 8, «Меры контроля воздействия и средства индивидуальной защиты», и раздел 13, «Условия удаления в отходы».

Паспорт безопасности материала
Дата вступления в силу: *июнь 2020 г.*
Отменяет версию документа за: январь 2020 г.

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Раздел 7: Правила обращения и хранения

7.1 Меры предосторожности при обращении с продуктом

Обращение Особое обращение не требуется. В случае разбития картриджа избегайте контакта с разлившимися реактивами. Избегать контакта с кожей и глазами.

7.2 Условия безопасного хранения и учет факторов несовместимости

Место хранения Хранить согласно указаниям на упаковке. Хранить в плотно закрытом контейнере/упаковке в прохладном, хорошо проветриваемом месте. Хранить вдали от несовместимых материалов.

7.3 Особые способы применения

См. раздел 1.2, «Рекомендованные способы применения».

Раздел 8: Меры контроля воздействия и средства индивидуальной защиты

8.1 Контрольные параметры

Предельно допустимые концентрации/рекомендации Для продуктов и компонентов не установлены предельно допустимые концентрации.

8.2 Меры контроля воздействия

Инженерно-технические мероприятия/средства контроля Следует обеспечить хорошую общую вентиляцию. Интенсивность вентиляции должна соответствовать условиям хранения/использования. Если возможно, используйте изолированное рабочее пространство, местную вытяжную вентиляцию и прочие инженерно-технические средства для сдерживания концентрации вещества в воздухе на уровне ниже ПДК. Если ПДК не установлены, поддерживайте приемлемые концентрации вещества в воздухе.

Индивидуальные средства защиты

Защита органов дыхания Соблюдайте рекомендации по использованию респираторов Управления охраны труда (OSHA) США, изложенные в документе 29 CFR 1910.134, или Европейского стандарта EN 149. При превышении ПДК или обнаружении признаков поражения используйте респираторы, одобренные Национальным институтом по безопасности и гигиене труда (NIOSH) США, Управлением по безопасности и охране труда в добывающей промышленности (MSHA) США или Европейским стандартом EN 149.

Защита глаз/лица Носите очки химической защиты.

Защита кожных покровов/тела При работе в лаборатории для сведения к минимуму риска контакта с кожей используйте перчатки и халат.

Защита окружающей среды Соблюдайте общие правила работы на объекте и удаления отходов.

Раздел 9: Физические и химические свойства

9.1 Информация о физических и химических свойствах

Описание материала			
Физическая форма	Жидкость	Внешний вид/описание	Красители представляют собой растворы с вариабельным цветом, компоненты не имеют запаха.
Цвет	Вариабельный	Запах	Без запаха
Порог ощущения запаха	Данные отсутствуют		
Общие свойства			
Точка кипения	100 °C (212 °F)	Температура плавления/ замерзания	0 °C (32 °F)
Температура разложения	Данные отсутствуют	pH	от 6 до 9
Удельный вес/относительная плотность	Данные отсутствуют	Растворимость в воде	Данные отсутствуют
Вязкость	Данные отсутствуют	Взрывчатые свойства	Данные отсутствуют
Окислительные свойства:	Данные отсутствуют		
Летучесть			
Давление паров	Данные отсутствуют	Плотность паров	Данные отсутствуют
Интенсивность испарения	Данные отсутствуют		
Воспламеняемость			
Температура вспышки	Данные отсутствуют	ВКПВ (верхний предел взрываемости)	Данные отсутствуют
НПВ (нижний предел взрываемости)	Данные отсутствуют	Самовоспламенение	Данные отсутствуют
Воспламеняемость (в твердом, газообразном состоянии)	Данные отсутствуют		
В отношении окружающей среды			
Коэффициент распределения октанол/вода	Данные отсутствуют		

9.2 Дополнительная информация

Дополнительные физические и химические свойства не обнаружены.

Раздел 10: Стабильность и реакционная способность

10.1 Реакционная способность

В нормальных условиях использования опасные реакции неизвестны.

10.2 Химическая стабильность

Стабильно

10.3 Вероятность опасных реакций

Опасная полимеризация не происходит.

10.4 Условия, которых следует избегать

Данные отсутствуют

10.5 Несовместимые материалы

Данные отсутствуют

10.6 Опасные продукты разложения

Данные отсутствуют

Раздел 11: Токсикологическая информация

11.1 Информация о токсикологических последствиях

Свойства (СГС)	Классификация
Острая токсичность	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Разъедающее/раздражающее воздействие на кожу	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Серьезное повреждение/раздражение глаз	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Сенсибилизация кожи	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Сенсибилизация органов дыхания	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Опасность при аспирации	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Канцерогенность	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Мутагенность для зародышевых клеток	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Токсическое действие на репродуктивную функцию	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Органоспецифическая токсичность при однократном воздействии (STOT-SE)	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Органоспецифическая токсичность при многократном воздействии (STOT-RE)	**EU/CLP**•Данные отсутствуют **СГС ООН 3**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют

Возможные последствия для здоровья

Вдыхание
Острые последствия Симптомов не ожидается.
Хронические последствия Данные отсутствуют
Кожа
Острые последствия Симптомов не ожидается.
Хронические последствия Данные отсутствуют

Глаза	
Острые последствия	Симптомов не ожидается.
Хронические последствия	Данные отсутствуют
Проглатывание	
Острые последствия	Данные отсутствуют
Хронические последствия	Данные отсутствуют

Раздел 12: Информация о воздействии на окружающую среду

12.1 Токсичность

Данные о материале отсутствуют.

12.2 Устойчивость и способность к разложению

Данные о материале отсутствуют.

12.3 Способность к биоаккумуляции

Данные о материале отсутствуют.

12.4 Подвижность в почве

Данные о материале отсутствуют.

12.5 Результаты оценки соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества»

Оценка соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества» не производилась.

12.6 Другие неблагоприятные последствия

Исследования не проводились.

Раздел 13: Условия удаления в отходы

13.1 Методы переработки отходов

Отходы продукта	Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.
Отходы упаковки	Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

13.2 Дополнительная информация

С биологическими образцами, смешанными с гранулами, следует обращаться как с материалами, способными служить источником инфекционного заражения. По вопросам надлежащего удаления в отходы использованных образцов проконсультируйтесь с лицами, ответственными за обращение с отходами в вашей организации.

Раздел 14: Информация о транспортировке

	14.1 Номер ООН	14.2 Отгрузочное наименование ООН	14.3 Класс(-ы) опасности при транспортировке	14.4 Группа упаковки	14.5 Опасность для окружающей среды
DOT	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных
TDG	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных
IMO/IMDG	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных
IATA/ICAO	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных

14.6 Специальные меры предосторожности для пользователей

Не указаны.

14.7 Бестарная транспортировка в соответствии с Приложением II MARPOL 73/78 и Кодексом IBC

Данные отсутствуют.

Раздел 15: Нормативная информация

15.1 Правовые акты в сфере безопасности, защиты здоровья и окружающей среды/особые правовые акты, применимые к веществу или смеси

Класс опасности (SARA) Нет

15.2 Оценка химической безопасности

Оценка химической безопасности не проводилась.

Паспорт безопасности материала
Дата вступления в силу: *июнь 2020 г.*
Отменяет версию документа за: январь 2020 г.

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

Раздел 16: Дополнительная информация

Отказ от ответственности/ ограничение ответственности

Представленные выше сведения основаны на доступных нам данных и считаются верными. В связи с тем, что представленная информация может быть использована в независящих от нас и неизвестных нам условиях, мы не несем ответственность за последствия ее использования, а все лица, получающие эту информацию, должны самостоятельно принимать решения относительно последствий применения, свойств, средств защиты и способов удаления в отходы в соответствии с конкретными условиями применения. Мы не заявляем, не даем каких-либо гарантий и поручительств, явных или подразумеваемых (включая гарантии пригодности или товарной пригодности для конкретной цели), в отношении материалов и точности информации, полученных при их использовании результатов, а также опасностей, связанных с использованием данного материала. При обращении с материалом и его использовании следует проявлять осторожность. Представленная выше информация передана добросовестно с уверенностью в ее точности. Мы предоставляем всю информацию, касающуюся предполагаемого использования материала, по состоянию на момент публикации. Однако в случае нежелательных последствий, связанных с данным продуктом, настоящий паспорт безопасности материала не является и не может являться заменой консультации с обученным специалистом.

安全数据表

生效日期：2020 年 6 月
更换日期：2020 年 1 月

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

第 1 章：物质/混合物标识和公司/企业标识

1.1 产品识别

产品名称 Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C

产品代码 SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 物质或混合物的有关确定用途及不建议用途

有关确定用途 实验室使用

1.3 供应商安全数据表详情

制造商 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US：techsupport@cepheid.com

电话（通用） 1 (888) 838-3222 - 美国（选 2）

电话（通用） 1 (408) 541-4191 - 美国境外

供应商 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
欧盟：support@cepheideurope.com

电话（通用） 33 563 825 319 - 欧盟

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
澳大利亚
www.cepheidinternational.com
ANZ: TechSupportANZ@cepheid.com

电话（澳大利亚） 1800 107 884

1.4 紧急电话号码

制造商 1 (800) 535-5053 - INFOTRAC - 24 小时紧急电话

制造商 1 (352) 323-3500 - 美国境外

安全数据表
生效日期：2020 年 6 月
更换日期：2020 年 1 月

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

第 2 章：危险标识

EU/EEC
根据：第 1272/2008 号规章（欧共体）(CLP)/REACH 1907/2006 [修订版 453/2010]

2.1 物质或混合物的分类

CLP — 以下 SDS 适用于仅用于实验室的最终混合物成品。产品含有液体。例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
未分类

2.2 标签元素

CLP

危险声明 不要求标签元素

2.3 其他危险

CLP — 根据 (EC) 1272/2008 号条例 (CLP)，认为这种材料不是危险材料。

UN GHS 修订版 3
根据：联合国 (UN) 全球化学品统一分类和标签制度 (GHS)：第三次修订版

2.1 物质或混合物的分类

UN GHS — 以下 SDS 适用于仅用于实验室的最终混合物成品。产品含有液体。例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
未分类

2.2 标签元素

UN GHS

危险声明 不要求标签元素
防范声明

2.3 其他危险

UN GHS — 根据全球统一分类和标签制度（GHS），认为该产品不是危险品。

美国（US）
根据：OSHA 29 CFR 1910.1200 HCS

2.1 物质或混合物的分类

OSHA 的 HCS2012 — 以下 SDS 适用于仅用于实验室的最终混合物成品。产品含有液体。例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
未分类

2.2 标签元素

OSHA 的 HCS2012

危险声明 不要求标签元素

2.3 其他危险

OSHA 的 HCS2012 根据美国 OSHA 29 CFR 1910.1200 危害通识标准，认为该产品不是危险品。

加拿大
根据：WHMIS

2.1 物质或混合物的分类

WHMIS 以下 SDS 适用于仅用于实验室的最终混合物成品。产品含有液体。例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
未分类

2.2 标签元素

WHMIS 不要求标签元素。

2.3 其他危险

WHMIS 在加拿大，根据工作场所有害物质信息系统（WHMIS），认为上述产品不是危险品。

2.4 其他信息

整个颗粒浓度在染物组分中均低于 1%，或者根据美国危害通讯法规 (29 CFR 1910.1200)、欧盟物质或混合物分类与标签指令或全球物质或混合物分类与标签统一制度均不被规范为危险物质。

第 3 章：成分构成/信息

3.1 物质

成分在欧盟物质或混合物分类与标签指令或全球物质或混合物分类与标签统一制度均不被认为是危险物质。

3.2 混合物

材料不符合某种混合物的标准。

第 4 章：急救措施

4.1 急救措施描述

吸入 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。将受害者移至新鲜空气处。如果呼吸困难，就施用氧气。如果受害者吸入该物质，就不要使用口对口方法；借助配备单向阀或其他适当的呼吸医疗设备的袖珍面罩来给予人工呼吸。如果受害者没有呼吸，就给予人工呼吸。

皮肤 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。对于轻微的皮肤接触，避免使物质扩散到未受影响的皮肤上。在与物质接触的情况下，立即用流动的水冲洗眼睛至少 20 分钟。脱掉并隔离受污染的衣物。

眼睛 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。在与物质接触的情况下，立即用大量的水冲洗眼睛至少 20 分钟。如果眼睛刺激持续：获得医疗指导/就医治疗。

摄入 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。如果吞入，用水漱口（只有当伤员意识清楚时）。切勿催吐。如果受害者摄入该物质，请勿使用口对口人工呼吸法。如果摄入，立即就医。

4.2 急性及缓发的最重要症状及效应

请参阅第 11 章 - 毒物学信息。

4.3 任何需要立即就医及特别治疗的症候

对医生的注释 所有治疗措施均应根据所观察到的患者的痛苦症状和体征进行。应考虑可能发生过度暴露于非本品材料的可能性。

第 5 章：消防措施

5.1 灭火介质

适用的灭火介质 一旦发生火灾，请使用适合周围火情的介质。

不适用的灭火介质 无可用数据

5.2 由物质或混合物产生的特殊危险

异常火灾和爆炸危险 不易燃或不可燃。

有害燃烧产物 无可用数据

5.3 供消防队员采纳的建议

建筑消防员的防护服在火情中只能提供有限的保护；它在可能与物质直接接触的溢出情况下无效穿上制造商专门推荐的化学防护服。

穿上制造商专门推荐的化学防护服。它可能提供很少或根本没有提供热保护。

配戴正压自给式呼吸装置 (SCBA)。

小火：如果能够无风险地完成，就从火区移出容器。

第 6 章：意外释放措施

6.1 个人预防措施、防护装备和紧急程序

个人预防措施 万一盒子断裂，则适用于这些个人预防措施。使封闭的地区通风。穿戴适当的防护服。切勿踩踏泄漏物。除非穿着适当的防护服，否则不要触碰损坏的容器或溢出的物质。

应急程序 如果在一般条件下并且按照推荐的方法使用材料，预计不必要执行应急程序。

6.2 环保预防措施

避免流失到水道和下水道。

6.3 用于遏制/净化的方法和材料

遏制/净化措施 对于少量撒漏，戴手套并用纸巾吸附撒漏物。切勿将撒漏的材料冲刷到排水管道中予以处置。

6.4 其他各章的参考

请参阅第 8 章 - 接触控制/个人防护以及第 13 章 - 处置注意事项。

第 7 章：操作和贮存

7.1 用于安全操作的预防措施

操作 无需任何特殊操作。如果盒子断裂，避免接触撒漏的制剂。避免接触皮肤和眼。

7.2 包括任何不相容性的安全贮存条件

贮存 按产品标签予以贮存。将容器/包装在阴凉、通风良好之处保持密闭。远离不相容材料。

7.3 特定最终用途

请参阅第 1.2 条 - 有关确定用途。

第 8 章：接触控制/个人防护

8.1 控制参数

接触限值/指南 产品或组分无可用适用爆炸极限。

8.2 接触控制

工程措施/控制 应当使用良好的通用通风设施。通风速率应当与环境相配。如果适用，使用工艺外罩、局部排气通风或其它工程控制设施，以保持空气中的浓度低于推荐的接触限值。如果尚未确定接触限值，就将空气中的浓度保持在可接受的水平。

个人防护装备

呼吸 遵守 29 CFR 1910.134 或欧洲标准 EN 149 中可见的 OSHA 呼吸器条例。如果超过接触限值
或出现症状，就使用 NIOSH/MSHA 或欧洲标准 EN 149 认可的呼吸器。

眼睛/面部	佩戴防化学剂飞溅护目镜。
皮肤/身体	在实验室环境中，至少戴手套、穿实验服，以将皮肤接触降到最低。
环境接触控制	遵守厂区管理和废物处置最佳规范。

第 9 章：物理性质和化学性质

9.1 有关物理性质和化学性质的信息

材料描述			
外形	液体	外形/描述	染料是颜色各有不同的溶液，组分为无色。
颜色	各有不同	气味	无味
气味阈值	数据缺乏		
一般性质			
沸点	100 ° C (212 ° F)	熔点/凝固点	0 ° C (32 ° F)
分解温度	数据缺乏	pH 值	6 至 9
比重/相对密度	数据缺乏	水溶解度	数据缺乏
粘度	数据缺乏	易爆性质	数据缺乏
氧化性性质	数据缺乏		
挥发性			
蒸气压力	数据缺乏	蒸气密度	数据缺乏
蒸发速率	数据缺乏		
易燃性			
闪点	数据缺乏	爆炸上限	数据缺乏
爆炸下限	数据缺乏	自燃点	数据缺乏
易燃性（固体、气体）	数据缺乏		
环境方面			
辛醇/水分配系数	数据缺乏		

9.2 其他信息

未注明额外的物理和化学参数。

第 10 章：稳定性和反应性

10.1 反应性

在正常使用条件下，未知有危险反应。

10.2 化学稳定性

稳定

10.3 危险反应的可能性

不会发生危险的聚合反应。

10.4 应避免的情况

无可用数据

10.5 不相容的材料

无可用数据

10.6 危险的分解产物

无可用数据

第 11 章：毒物学信息

11.1 有关毒物学效应的信息

GHS 危险种类	危险类别
急性毒性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
皮肤腐蚀/刺激	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
严重眼损伤/刺激	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
皮肤过敏	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
呼吸过敏	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
吸入危险	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
致癌性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
生殖细胞致突变性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
针对生殖的毒性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-SE	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-RE	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据

潜在健康影响

吸入	
急性（立即）	无预期症状。
慢性（缓发）	无可用数据
皮肤	
急性（立即）	无预期症状。
慢性（缓发）	无可用数据
眼睛	
急性（立即）	无预期症状。
慢性（缓发）	无可用数据
摄入	
急性（立即）	无可用数据
慢性（缓发）	无可用数据

第 12 章：生态学信息

12.1 毒性

材料数据缺失。

12.2 持久性和降解性

材料数据缺失。

12.3 生物累积的潜力

材料数据缺失。

12.4 土壤中的移动性

材料数据缺失。

12.5 PBT 及 vPvB 评估的结果

尚未进行 PBT 和 vPvB 评估。

12.6 其他不良效应

未发现研究成果。

第 13 章：处置注意事项

13.1 废物处理方法

产品废物	与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。
包装废弃物	与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。

13.2 其他信息

与露珠混合的生物标本应以能够传递感染源对待。有关已用标本的正确处置，请查询贵机构的环境废弃物人员。

第 14 章：运输信息

	14.1 UN 编号	14.2 UN 正式运输名称	14.3 运输危险分类	14.4 包装组	14.5 环境危害
DOT	NDA	未管制	NDA	NDA	NDA
TDG	NDA	未管制	NDA	NDA	NDA
IMO/IMDG	NDA	未管制	NDA	NDA	NDA
IATA/ICAO	NDA	未管制	NDA	NDA	NDA

14.6 用户特殊防护措施

未列明。

14.7 根据 MARPOL73/78 的附录 II 和 IBC 准则散装运输

缺乏数据。

第 15 章：法规信息

15.1 针对特定物质或混合物的安全、卫生和环境条例/法规

SARA 危险性分类 无

15.2 化学安全评估

未进行化学安全评估。

第 16 章：其他信息

免责声明/责任声明

以上信息基于对于我们的可用数据，而且相信是正确的。由于对信息的应用可能会在超出我们控制的条件下和以我们所不熟悉的条件进行，因此我们对其使用的任何结果概不承担任何责任，而且收到此信息的所有人士均务必自行确定其特定应用条件下的效能、性能、防护和处置方法。未就信息所涵盖的材料、其准确性、因使用材料而获得的结果或与使用材料相关的危害作出任何明示或暗示的表示、担保或保证（包括对特定目的下适用性或适销性的担保）。操作或使用本材料应小心谨慎。以上信息以诚信提供，而且相信是准确的。截至签发日期，我们提供有关可预见材料操作的所有信息。然而，一旦发生与本品相关的恶性事故，本安全数据表却不是，而且也不旨在是向接受过适当训练人员咨询的替代。

略语表
NDA = 无可用数据

安全データシート
発効日:2020 年 6 月
優先日付:2020 年 1 月

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

セクション 1:物質・混合物、および企業・事業の識別

1.1 製品識別子

製品名 **Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C**

製品コード SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

1.2 物質や混合物の特定された関連用途、および推奨されない用途

特定された関連用途 研究用

1.3 安全データを提供した供給業者の詳細

製造業者 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US:techsupport@cepheid.com
電話(一般) 1 (888) 838-3222 -米国オプション 2
電話(一般) 1 (408) 541-4191 -米国外

供給業者 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
EU:support@cepheideurope.com
電話(一般) 33 563 825 319 - EU

Cepheid Holdings Pty Ltd
23-27 Chaplin Drive
Lane Cove West NSW 2066
オーストラリア
www.cepheidinternational.com
ANZ:TechSupportANZ@cepheid.com
電話番号 (オーストラリア) 1800 107 884

1.4 緊急電話番号

製造業者 1 (800) 535-5053 - INFOTRAC - 24 時間緊急電話
製造業者 1 (352) 323-3500 - 米国外

安全データシート
発効日:2020 年 6 月
優先日付:2020 年 1 月

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

セクション 2:危険性識別

EU/EEC

準拠:指令(EC)1272/2008 (CLP)/REACH 1907/2006 [453/2010 による改訂]

2.1 物質や混合物の分類

CLP

次の SDS は、研究所で使用される最終完全混合物製品用のみです。本製品には液体が含まれています。一部の物質の情報の開示の免除は、CLP 第 1 条(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
未分類

2.2 ラベル要素

CLP

危険有害性情報 ラベル要素は必要ありません。

2.3 その他危険性

CLP

規定(EC) No. 1272/2008 (CLP) に準じて、本剤は危険物とみなされません。

UN GHS 改訂第 3 版

準拠:UN 化学品の分類および表示に関する世界調和システム(GHS) 改訂第 3 版

2.1 物質や混合物の分類

UN GHS

次の SDS は、研究所で使用される最終完全混合物製品用のみです。本製品には液体が含まれています。一部の物質の情報の開示の免除は、CLP 第 1 条(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
未分類

2.2 ラベル要素

UN GHS

危険有害性情報 ラベル要素は必要ありません。
予防情報

2.3 その他危険性

UN GHS

危険化学品分類表示の世界調和システム(GHS)では、本製品は危険な物質とみなされません。

米国(US)

準拠:OSHA 29 CFR 1910.1200 HCS

2.1 物質や混合物の分類

OSHA HCS 2012

次の SDS は、研究所で使用される最終完全混合物製品用のみです。本製品には液体が含まれています。一部の物質の情報の開示の免除は、CLP 第 1 条(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
未分類

2.2 ラベル要素

OSHA HCS 2012

危険有害性情報 ラベル要素は必要ありません。

2.3 その他危険性

OSHA HCS 2012 本製品は、U.S. OSHA 29 CFR 1910.1200 危険有害性周知基準に基づいた場合、危険物とみなされません。

カナダ
準拠:WHMIS

2.1 物質や混合物の分類

WHMIS 次の SDS は、研究所で使用される最終完全混合物製品用のみです。本製品には液体が含まれています。一部の物質の情報の開示の免除は、CLP 第 1 条(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
未分類

2.2 ラベル要素

WHMIS ラベル要素は必要ありません。

2.3 その他危険性

WHMIS カナダでは、上述の製品は作業場にある危険物に関する情報システム (WHMIS)に基づき危険物と
みなされません。

2.4 その他情報

染料の成分は、全品目の 1%未満であるか、または米国ハザード通信規制(29 CFR 1910.1200)、物質または混合物の分類と表示に関する EU 指令、または物質または混合物の分類と表示に関する世界調和システムで有害とみなされていません。

セクション 3:成分の組成・情報

3.1 物質

成分は、物質または混合物の分類と表示に関する EU 指令、または物質または混合物の分類と表示に関する世界調和システムで有害とみなされていません。

3.2 混合物

本剤は、混合物区分を満たしません。

セクション 4:応急処置手段

4.1 応急措置手段

吸引
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。被災者を新鮮な空気がある場所に移す。呼吸困難の場合は酸素を供給する。被災者が物質を吸引した場合、口移し式人工呼吸を行ってはならない;一方向バルブの付いたポケットマスクや、その他の適切な呼吸医療装置を使って人工呼吸を行う。被災者が呼吸していない場合は、人工呼吸を施す。

皮膚
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。軽度の皮膚との接触では、影響を受けていない皮膚に物質を広げないようにする。物質と接触した場合は、最低 20 分間、直ちに流水で皮膚を洗浄する。汚染した衣類を取り除いて隔離する。

目
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。物質と接触した場合は、最低 20 分間、直ちに流水で目を洗浄する。目の刺激が続く場合:医師の助言/手当てを受ける。

摂取
物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。飲み込んだ場合は、水で口をゆすいではならない(意識がある場合)。嘔吐を誘発しないでください。被災者が物質を摂取した場合は口移し式人工呼吸を行ってはならない。摂取した場合は直ちに医師の手当てを受ける。

4.2 もっとも重要な症状と影響、急性および遅発性

第十一項 毒性に関する情報を参照してください。

4.3 直ちに医学的配慮と特別治療を必要とする兆候

医師へのメモ
治療はすべて、患者の苦痛の兆候および症状に基づき行われる必要があります。本製品以外の物質に著しくさらされた可能性について考慮する必要があります。

セクション 5:消化手段

5.1 消火剤

適切な消火剤
火災が発生した場合は、周辺の火災に適切な方法を用いてください。

不適切な消火剤
データなし

5.2 物質や混合物から発生する特別な危険

異常な火災と爆発の危険
引火性または可燃性ではありません。

有害な燃焼生物
データなし

5.3 消防士への助言

流出した状況では物質に直接接触する可能性があ るため、効果がない製造業者が推奨する 化学品防護服を着用する。
製造業者が推奨する化学品防護服を着用する。熱に対する保護は、ある程度、またはまったく提供されない。
陽圧自給式呼吸器(SCBA)を着用する。
小規模火災:危険を冒さずにできる場合は、火災区域から容器を移動させる動かす。

セクション 6:漏出時の措置

6.1 人体に対する注意事項、保護具、および緊急時措置

人体に対する注意事項 カートリッジが破損した場合、これらの人体に対する予防措置が適用されます。閉じ込められた場所を換気する。適切な保護服を着用する。漏出した物質を通って歩かない。適切な保護服を着用せずに破損した容器または漏出した物質に触れてはならない。

応急措置 物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されない。

6.2 影響に対する注意事項

排水溝や下水道に流れ込まないようにしてください。

6.3 閉じ込めと清掃の手段と物質

閉じ込めと清掃の手段 少量の流出の場合は、手袋を着用し、ペーパータオルで流出を吸収してください。流出した物質を排水溝に廃棄しないでください。

6.4 他のセクションへの言及

第八項 爆発管理/安全保護、および第十三項 廃棄時の注意事項を参照してください。

セクション 7:取り扱いと保管

7.1 安全な取り扱いについての注意

取り扱い 特別な取扱いは必要ありません。カートリッジが破損した場合、漏出した試薬に触れないようにしてください。皮膚に付着したり、目に入らないようにしてください。

7.2 安全な保管の条件、不適合性を含む

保管 製品ラベルに従って保管してください。容器/パッケージをしっかりと密閉し、涼しく、風通しの良い場所に保管してください。互換性をもたない物質から離す。

7.3 具体的な最終用途

セクション 1.2 関連する使用方法に関する情報を参照してください。

セクション 8:暴露管理・個人保護

8.1 管理パラメータ

曝露限度/ガイドライン 製品または成分に規定の曝露限度がありません。

8.2 曝露管理

工学的手段・管理 十分な通気を確保してください。通規率は状況に応じて適切に調整してください。該当する場合は、包囲装置、局所排気装置、またはその他のエンジニアリングコントロール装置を使って、空気中の粉塵レベルが推奨暴露限界を超えないようにしてください。暴露レベルが確定されていない場合は、許容範囲の粉塵量を維持してください。

個人用保護具

呼吸器官	OSHA 呼吸器規制に関しては、29 CFR 1910.134 または 欧州標準 EN 149 をご覧ください。暴露基準を超える場合、あるいは症状が発症した場合は、NIOSH/MSHA または 欧州標準 EN 149 保護マスクをご使用ください。
目・顔面	化学物飛散防止ゴーグルを着用してください。
皮膚・人体	研究所での服装として、手袋とラボコートを最低限着用し、皮膚接触を最小化してください。
環境暴露管理	現場管理および廃棄物の取り扱いは十分注意して行ってください。

セクション 9:物理的および化学的特性

9.1 物理的および化学的特性

材料の説明			
物理的形状	液体	外観/記述	染料は種々の色の溶液であり、成分は無臭です。
色	変化する	臭気	無臭
臭気限界	データ不足		
一般的性質			
沸騰点	100 ° C (212 ° F)	融解点・凝固点	0 ° C (32 ° F)
分解温度	データ不足	pH	6～9
比重・相対密度	データ不足	水溶性	データ不足
粘性	データ不足	爆発特性	データ不足
酸化特性:	データ不足		
揮発度			
蒸気圧	データ不足	蒸気密度	データ不足
蒸発速度	データ不足		
可燃性			
引火点	データ不足	UEL	データ不足
LEL	データ不足	自己発火	データ不足
可燃性(固体、ガス)	データ不足		
環境曝露管理			
オクタノール・水分配係数	データ不足		

9.2 その他情報

その他に物理的および化学的パラメータの記載はありません。

セクション 10:安定性と反応性

10.1 反応性

通常の使用において、危険反応は報告されていません。

10.2 化学安定性

安定

10.3 有害反応の可能性

危険物のポリメリゼーションは発生しません。

10.4 回避すべき条件

データなし

10.5 不適合物質

データなし

10.6 有害分解性生物

データなし

セクション 11:毒性情報

11.1 毒性効果

GHS 特性	分類
急性毒性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
皮膚の腐食・炎症	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
重度の目の損傷・炎症	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
皮膚感作性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
呼吸器感作性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
吸引有害性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
発癌性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
生殖細胞変異原性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
生殖毒性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足

GHS 特性	分類
STOT-SE	EU/CLP･データ不足 UN GHS 3･データ不足 OSHA HCS 2012･データ不足
STOT-RE	EU/CLP･データ不足 UN GHS 3･データ不足 OSHA HCS 2012･データ不足

考えられる健康への影響

吸引
急性(即座) 症状は期待されない。
慢性(遅発性) データなし
皮膚
急性(即座) 症状は期待されない。
慢性(遅発性) データなし
目
急性(即座) 症状は期待されない。
慢性(遅発性) データなし
摂取
急性(即座) データなし
慢性(遅発性) データなし

セクション 12:生態学的情報

12.1 毒性
実態データが不足しています

12.2 持続性と分解性
実態データが不足しています

12.3 生体内蓄積能
実態データが不足しています

12.4 土壌中移動性
実態データが不足しています

12.5 PBT と vPvB 評価の結果
PBT および vPvB アセスメントは行われていません。

12.6 その他有害影響
そのような研究結果はありません。

セクション 13:廃棄上の注意

13.1 廃棄物処理手段

製品廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

包装廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

13.2 その他情報

ビーズと混合された生物試料は、感染物質を伝染する能力があるものとして取り扱われる必要があります。使用済み試料の適切な廃棄方法については、機関の環境廃棄物担当員に相談してください。

セクション 14:輸送情報

	14.1 UN 番号	14.2 UN 正式輸送品目名	14.3 輸送有害性等級	14.4 包装等級	14.5 環境有害性
DOT	NDA	規制なし	NDA	NDA	NDA
TDG	NDA	規制なし	NDA	NDA	NDA
IMO/IMDG	NDA	規制なし	NDA	NDA	NDA
IATA/ICAO	NDA	規制なし	NDA	NDA	NDA

14.6 ユーザーに対する特別予防装置

指定なし。

14.7 MARPOL 73/78 の付属書 II と IBC コードに則ったバルク輸送

データ不足。

セクション 15:規制情報

15.1 物質や混合物についての具体的な安全、健康、環境規制・法律

SARA 危険分類 なし

15.2 化学物質安全評価

化学的安全評価は実施されていません。

安全データシート
発効日:2020 年 6 月
優先日付:2020 年 1 月

Calibration Dyes and Buffer C
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セクション 16:その他情報

免責条項/責任声明

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略語について
NDA = 該当データなし。

Cepheid

Safety Data Sheet
Effective Date: September, 2016
Supersedes Date: November, 2015

Xpert Trichomonas

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifier

Product Name **Xpert Trichomonas**
Product Code 900-0657; GXTV-10; GXTV-CE-10

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Relevant Identified Use(s) Laboratory use

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US: techsupport@cepheid.com
Telephone (General) 1 (888) 838-3222 - US Option 2
Telephone (General) 1 (408) 541-4191 - Outside of the US

1.4 Emergency Telephone Number

Manufacturer 1 (800) 424-9300 - CHEMTREC - 24 hr Emergency
Manufacturer 1 (703) 741-5500 - Outside of the US

Section 2: Hazards Identification

EU/EEC

According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the Substance or Mixture

CLP The following SDS is for the final finished product only as used in the laboratory. It contains liquid components, some of which are in freeze-dried powders and reagents which are contained in the cartridge and in a Nalgene bottle. All reagents are clear, colorless liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Not classified

2.2 Label Elements

CLP

Hazard Statements No label element(s) required

2.3 Other Hazards

CLP According to Regulation (EC) No. 1272/2008 (CLP) this material is not considered hazardous.

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2.1 Classification of the Substance or Mixture

UN GHS

Acute Toxicity Oral 5
Skin Mild Irritation 3
Eye Irritation 2

2.2 Label Elements

UN GHS

WARNING

Hazard Statements

May be harmful if swallowed
Causes mild skin irritation
Causes serious eye irritation

Precautionary Statements

Prevention

Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response

Call a POISON CENTER or doctor/physician if you feel unwell.
If skin irritation occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

2.3 Other Hazards

UN GHS

According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous.

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the Substance or Mixture

OSHA HCS 2012

Eye Irritation 2

2.2 Label Elements

OSHA HCS 2012

WARNING

Hazard Statements

Causes serious eye irritation

Precautionary Statements

Prevention

Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

2.3 Other Hazards

OSHA HCS 2012 Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

Canada
According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS Other Toxic Effects - D2B

2.2 Label Elements

WHMIS

Other Toxic Effects - D2B

2.3 Other Hazards

WHMIS In Canada, the product mentioned above is considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).

2.4 Other Information

This SDS is for the final finished product only as used in the laboratory or clinical setting. This product is a cartridge that contains liquid reagents and freeze dried powders. Hazards represented are based on the reagents contained in the cartridge. No exposure to the reagents in this cartridge is expected during normal use.

Section 3: Composition/Information on Ingredients

3.1 Substances

Material does not meet the criteria of a substance.

3.2 Mixtures

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Guanidine thiocyanate	**CAS:** 593-84-0 **EINECS:** 209-812-1	5% TO 10%	NDA	**UN GHS:** Acute Tox. 4 (Orl); Skin Irrit. 3; Eye Irrit. 2B; Aquatic Acute 3; Aquatic Chronic 3 **EU CLP:** Acute Tox. 4, H302; EUH031; Aquatic Chronic 3, H412 **OSHA HCS 2012:** Acute Tox. 4 (Orl); Eye Irrit. 2B	NDA
Glycerol	**CAS:** 56-81-5 **EC Number:** 200-289-5	1% TO 5%	Ingestion/Oral-Rat LD50 • 12600 mg/kg	**UN GHS:** Eye Irrit. 2; Skin Irrit. 3 **EU CLP:** Eye Irrit. 2, H319 **OSHA HCS 2012:** Eye Irrit. 2	NDA

See Section 16 for full text of H-statements.

Section 4: First Aid Measures

4.1 Description of First Aid Measures

Inhalation First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move victim to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing.

Skin First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. For minor skin contact, avoid spreading material on unaffected skin. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Remove and isolate contaminated clothing.

Eye First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. If swallowed, rinse mouth with water (only if the person is conscious) Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Obtain medical attention immediately if ingested.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Refer to Section 11 - Toxicological Information.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media LARGE FIRES: Dry chemical, CO_2, alcohol-resistant foam or water spray.
SMALL FIRES: Dry chemical, CO_2 or water spray.

Unsuitable Extinguishing Media No data available

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards May emit toxic vapors of carbon oxides, sulfur oxides, nitrogen oxides.

Hazardous Combustion Products No data available

5.3 Advice for Firefighters

Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.
Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.
Wear positive pressure self-contained breathing apparatus (SCBA).
SMALL FIRES: Move containers from fire area if you can do it without risk.

Section 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions In the event a cartridge is broken these personal precautions are applicable. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate enclosed areas.

Emergency Procedures No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

6.3 Methods and Material for Containment and Cleaning Up

Containment/ Clean-up Measures For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.

6.4 Reference to Other Sections

Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7: Handling and Storage

7.1 Precautions for Safe Handling

Handling No special handling necessary. If cartridge is broken avoid contact with spilled reagents. Avoid contact with skin and eyes eyes.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Storage Store according to product labeling. Keep away from incompatible materials. Store locked up. Keep container/package tightly closed in a cool, well-ventilated place.

7.3 Specific End Use(s)

Refer to Section 1.2 - Relevant identified uses.

Section 8: Exposure Controls/Personal Protection

8.1 Control Parameters

Exposure Limits/Guidelines		
	Result	**OSHA**
Glycerol (56-81-5)	TWAs	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)
Guanidine thiocyanate	TWAs	5 mg/m3 TWA (as CN) *as Cyanide compounds*

8.2 Exposure Controls

Engineering Measures/Controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face Wear chemical splash safety goggles.

Skin/Body Wear protective clothing

Environmental Exposure Controls Follow best practice for site management and disposal of waste.

Key to abbreviations
OSHA = Occupational Safety and Health Administration
TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Beads are solid white components in cartridges; reagents are clear liquids which are primarily buffered in aqueous solutions. Components are odorless.
Color	White/clear	Odor	Odorless
Odor Threshold	Data lacking		
General Properties			
Boiling Point	100 °C (212 °F)	Melting Point/Freezing Point	0 °C (32 °F)
Decomposition Temperature	Data lacking	pH	7 to 9 Lysis reagent #1 (GTC pH (3.7-4.1.)) Lysis reagent #2 (sodium hydroxide <1% pH 14).
Specific Gravity/Relative Density	Data lacking	Water Solubility	Data lacking
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Data lacking	Vapor Density	Data lacking
Evaporation Rate	Data lacking		
Flammability			
Flash Point	360 to 560 °F (182.2222 to 293.3333 °C) (Binding reagent)	UEL	Data lacking
LEL	Data lacking	Autoignition	Data lacking
Flammability (solid, gas)	Data lacking		
Environmental			
Octanol/Water Partition Coefficient	Data lacking		

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical Stability

Stable

10.3 Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4 Conditions to Avoid

Incompatible materials. Heat, contact with acids or bleach may liberate very toxic gas.

10.5 Incompatible Materials

Acids, oxidizing agents.

10.6 Hazardous Decomposition Products

Carbon oxides, sodium oxides.

Section 11: Toxicological Information

11.1 Information on Toxicological Effects

Components		
Guanidine thiocyanate (5% TO 10%)	593-84-0	**Acute Toxicity:** Intraperitoneal-Mouse LD50 • 300 mg/kg
Glycerol (1% TO 5%)	56-81-5	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 12600 mg/kg; *Behavioral*: **General anesthetic**; *Behavioral*: **Muscle weakness**; *Liver*: **Other changes**; **Irritation:** Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation; **Multi-dose Toxicity:** Ingestion/Oral-Mouse TDLo • 560 g/kg 8 Week(s)-Continuous; *Lungs, Thorax, or Respiration*: **Structural or functional change in trachea or bronchi**; Ingestion/Oral-Mouse TDLo • 2800 mg/kg 25 Week(s)-Continuous; *Skin and Appendages: Other*: **Tumors**; *Tumorigenic*: **Facilitates action of known carcinogen**; **Mutagen:** Cytogenetic analysis • Ingestion/Oral-Rat • 1 g/kg; DNA Inhibition • Unreported Route-Human • Lymphocyte (Somatic cell) • 200 mmol/L; **Reproductive:** Ingestion/Oral-Rat TDLo • 100 mg/kg (1D male); *Reproductive Effects: Effects on Fertility*: **Post-implantation mortality**; **Tumorigen / Carcinogen:** Ingestion/Oral-Mouse TDLo • 87.5 g/kg 25 Week(s)-Intermittent; *Tumorigenic*: **Equivocal tumorigenic agent by RTECS criteria**; *Lungs, Thorax, or Respiration*: **Tumors**; *Tumorigenic*: **Facilitates action of known carcinogen**

GHS Properties	Classification
Acute Toxicity	**EU/CLP**•Data lacking **UN GHS**•Acute Toxicity - Oral 5 - ATEmix (oral) = 5000 mg/kg **OSHA HCS 2012**•Data lacking
Skin Corrosion/Irritation	**EU/CLP**•Data lacking **UN GHS**•Skin Mild Irritation 3 **OSHA HCS 2012**•Data lacking
Serious Eye Damage/Irritation	**EU/CLP**•Data lacking **UN GHS**•Eye Irritation 2 **OSHA HCS 2012**•Eye Irritation 2
Skin Sensitization	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Respiratory Sensitization	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Aspiration Hazard	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Carcinogenicity	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Germ Cell Mutagenicity	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Toxicity for Reproduction	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking

GHS Properties	Classification
STOT-SE	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-RE	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking

Potential Health Effects

Inhalation
Acute (Immediate) May cause irritation.
Chronic (Delayed) No data available
Skin
Acute (Immediate) Causes mild skin irritation.
Chronic (Delayed) No data available
Eye
Acute (Immediate) Causes serious eye irritation.
Chronic (Delayed) No data available
Ingestion
Acute (Immediate) May be harmful if swallowed.
Chronic (Delayed) No data available

Key to abbreviations
LD = Lethal Dose
TD = Toxic Dose

Section 12: Ecological Information

12.1 Toxicity

Guanidinium thiocyanate is harmful to aquatic life.

12.2 Persistence and Degradability

Material data lacking.

12.3 Bioaccumulative Potential

Material data lacking.

12.4 Mobility in Soil

Material data lacking.

12.5 Results of PBT and vPvB Assessment

No PBT and vPvB assessment has been conducted.

12.6 Other Adverse Effects

No studies have been found.

Section 13: Disposal Considerations

13.1 Waste Treatment Methods

Product Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13.2 Other Information

Biological specimens, including used cartridges, should be treated as capable of transmitting infectious agents. Consult your institution's environmental waste personnel on proper disposal of used cartridges and unused reagents. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions outside the USA should check their country hazardous waste disposal requirements.

Section 14: Transport Information

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Transport Hazard Class(es)	14.4 Packing Group	14.5 Environmental Hazards
DOT	NDA	Not Regulated	NDA	NDA	NDA
TDG	NDA	Not Regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not Regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not Regulated	NDA	NDA	NDA

14.6 Special Precautions for User

None specified.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Data lacking.

Section 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SARA Hazard Classifications Acute, Fire

Inventory						
Component	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Glycerol	56-81-5	Yes	No	Yes	No	Yes
Guanidine thiocyanate	593-84-0	Yes	No	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

•Glycerol	56-81-5	Uncontrolled product according to WHMIS classification criteria
•Guanidine thiocyanate	593-84-0	Not Listed

Canada - WHMIS - Ingredient Disclosure List

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

Environment

Canada - CEPA - Priority Substances List

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

United States- California

Environment

U.S. - California - Proposition 65 - Carcinogens List		
•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Glycerol	56-81-5	Not Listed
•Guanidine thiocyanate	593-84-0	Not Listed

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16: Other Information

Relevant Phrases (code & full text)

H302 - Harmful if swallowed
H412 - Harmful to aquatic life with long lasting effects
EUH031 - Contact with acids liberates toxic gas.

Disclaimer/ Statement of Liability

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections, and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained.

Key to abbreviations
NDA = No data available

Fiche de données de sécurité *Xpert Trichomonas*
Date d'entrée en vigueur : Septembre 2016
Remplace la date : Novembre 2015

Section 1 : Identification de la substance/du mélange et de la compagnie/entreprise

1.1 Identifiant de produit

Nom du produit **Xpert Trichomonas**
Code de produit 900-0657 ; GXTV-10 ; GXTV-CE-10

1.2 Utilisations pertinentes identifiées de la substance ou du mélange et utilisations contre-indiquées

Utilisation(s) pertinente(s) identifiée(s) Utilisation en laboratoire

1.3 Coordonnées du fournisseur de la fiche de données de sécurité (FDS)

Fabricant Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
États-Unis
www.cepheid.com
États-Unis : techsupport@cepheid.com
Téléphone (général) 1 (888) 838-3222 - États-Unis Choix 2
Téléphone (général) 1 (408) 541-4191 - En dehors des États-Unis

1.4 Numéro de téléphone d'urgence

Fabricant 1 (800) 424-9300 - CHEMTREC - Urgences 24 h/24
Fabricant 1 (703) 741-5500 - En dehors des États-Unis

Section 2 : Identification des risques

EU/EEC

Selon : Règlement (CE) N° 1272/2008 (CLP)/REACH 1907/2006 [modifié par le 453/2010]

2.1 Classification de la substance ou mélange

CLP La fiche de données de sécurité (FDS) suivante concerne uniquement le produit fini final, tel qu'utilisé au laboratoire. Il contient des composants liquides dont certains sont des poudres lyophilisées et des réactifs qui sont contenus dans la cartouche et dans un flacon en Nalgène. Tous les réactifs sont des liquides incolores et limpides. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classé

2.2 Éléments de l'étiquette

CLP

Mentions de danger Aucune étiquette(s) requise

2.3 Autres dangers

CLP Selon le règlement (CE) N° 1272/2008 (CLP), ce produit n'est pas considéré dangereux.

SGH ONU

Selon : Système général harmonisé (SGH) des Nations Unies concernant la classification et l'étiquetage des produits chimiques

2.1 Classification de la substance ou mélange

SGH ONU
Toxicité aiguë par voie orale 5
Légère irritation cutanée 3
Irritation oculaire 2

2.2 Éléments de l'étiquette

SGH ONU

ATTENTION

Mentions de danger
Nocif en cas d'ingestion
Provoque une légère irritation de la peau
Provoque une irritation oculaire grave

Mises en garde

Prévention
Se laver soigneusement après manipulation.
Porter des gants de protection/des vêtements de protection/une protection oculaire/une protection faciale.

Réponse
Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.
En cas d'irritation cutanée : consulter un médecin.
EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer.
Si l'irritation oculaire persiste : consulter un médecin.

2.3 Autres dangers

SGH ONU Selon le Système général harmonisé de classification et d'étiquetage (SGH), ce produit est considéré dangereux.

États-Unis (É.-U.)

Selon : OSHA 29 CFR 1910.1200 HCS

2.1 Classification de la substance ou mélange

OSHA HCS 2012 Irritation oculaire 2

2.2 Éléments de l'étiquette

OSHA HCS 2012

ATTENTION

Mentions de danger	Provoque une irritation oculaire grave
Mises en garde	
Prévention	Se laver soigneusement après manipulation. Porter des gants de protection/des vêtements de protection/une protection oculaire/une protection faciale.
Réponse	EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer. Si l'irritation oculaire persiste : consulter un médecin.

2.3 Autres dangers

OSHA HCS 2012 En vertu des réglementations des États-Unis (29 CFR 1910.1200 - Norme de communication des dangers), ce produit est considéré dangereux.

Canada
Selon : WHMIS

2.1 Classification de la substance ou mélange

WHMIS Autres effets toxiques - D2B

2.2 Éléments de l'étiquette

WHMIS

Autres effets toxiques - D2B

2.3 Autres dangers

WHMIS Au Canada, le produit mentionné ci-dessus est considéré dangereux selon le Système d'information sur les matières dangereuses utilisées au travail (SIMDUT).

2.4 Autres informations

Cette FDS concerne uniquement le produit fini, tel qu'utilisé au laboratoire ou dans un cadre clinique. Ce produit consiste en une cartouche qui contient des réactifs liquides et des poudres lyophilisées. Les dangers représentés se basent sur les réactifs contenus dans la cartouche. Aucune exposition aux réactifs de cette cartouche n'est anticipée en usage normal.

Section 3 : Composition/informations sur les ingrédients

3.1 Substances

La matière ne répond pas aux critères d'une substance.

3.2 Mélanges

Composition					
Nom chimique	**Identifiants**	**%**	**DL50/LC50**	**Classifications selon réglementation/directive**	**Commentaires**
Thiocyanate de guanidinium	**CAS :** 593-84-0 **EINECS :** 209-812-1	5 % À 10 %	ADD	**SGH ONU :** Tox. aiguë 4 (voie orale) ; Irrit. peau 3 ; irrit. yeux 2B ; Aquatique Aigu 3 ; Aquatique Chronique 3 **EU CLP :** Tox. aiguë 4, H302 ; EUH031 ; Aquatique Chronique 3, H412 **OSHA HCS 2012 :** Tox. aiguë 4 (voie orale) ; Irrit. yeux 2B	ADD
Glycérol	**CAS :** 56-81-5 **Numéro CE :** 200-289-5	1 % À 5 %	Ingestion/voie orale-Rat DL50 • 12 600 mg/kg	**SGH ONU :** Irrit. yeux 2 ; Irrit. peau 3 **EU CLP :** Irrit. yeux 2, H319 **OSHA HCS 2012 :** Irrit. yeux 2	ADD

Voir la section 16 pour le texte complet des déclarations H.

Section 4 : Mesures de premier secours

4.1 Description des premiers soins

Inhalation Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. Déplacer la victime à l'air frais. Administrer de l'oxygène si la respiration est difficile. Ne pas faire de bouche-à-bouche si la victime a inhalé la substance ; pratiquer la respiration artificielle à l'aide d'un masque de poche doté d'une valve unidirectionnelle ou d'un autre dispositif médical respiratoire approprié. Pratiquer la respiration artificielle si la victime ne respire pas.

Peau Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact cutané mineur, éviter de répandre la matière sur la peau non affectée. En cas de contact avec la substance, rincer immédiatement la peau à l'eau courante pendant au moins 20 minutes. Retirer et isoler les vêtements contaminés.

Yeux Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact avec la substance, rincer immédiatement les yeux à l'eau courante pendant au moins 20 minutes. Si l'irritation oculaire persiste : consulter un médecin.

Ingestion Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas d'ingestion, rincer la bouche avec de l'eau (seulement si la victime est consciente). NE PAS faire vomir. Ne pas faire de bouche-à-bouche si la victime a ingéré la substance. Consulter immédiatement un médecin en cas d'ingestion.

4.2 Symptômes et effets les plus importants, aigus et différés

Voir la section 11 - Information toxicologique.

4.3 Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires

Notes pour le médecin Tous les traitements doivent être basés sur les signes et symptômes de détresse observés chez le patient. Il faut envisager la possibilité d'une surexposition à d'autres matières que ce produit.

Section 5 : Mesures de lutte contre l'incendie

5.1 Agents extincteurs

Agent extincteur convenable INCENDIES MAJEURS : poudre sèche, CO_2, mousse antialcool ou eau pulvérisée.
INCENDIES MINEURS : poudre sèche, CO_2, ou eau pulvérisée.

Agent extincteur inapproprié Aucune donnée disponible

5.2 Dangers particuliers résultant de la substance ou du mélange

Dangers inhabituels d'incendie et d'explosion Peut émettre des vapeurs toxiques d'oxydes de carbone, d'oxydes de soufre et d'oxydes d'azote.

Produits de combustion dangereux Aucune donnée disponible

5.3 Conseils aux pompiers

Les vêtements structurels de protection des pompiers fournissent une protection limitée UNIQUEMENT en cas d'incendie ; ils ne sont pas efficaces dans les cas de déversement où le contact direct avec la substance est possible. Porter des vêtements de protection chimique spécifiquement recommandés par le fabricant. Ceux-ci peuvent fournir peu ou pas de protection thermique.
Porter un appareil respiratoire autonome à pression positive (ARA).
INCENDIES MINEURS : enlever les conteneurs de la zone d'incendie si vous pouvez le faire sans risque.

Section 6 : Mesures en cas de fuite accidentelle

6.1 Précautions individuelles, équipement de protection et mesures d'urgence

Précautions individuelles Dans le cas où une cartouche est percée, ces précautions individuelles s'appliquent. Porter les vêtements de protection appropriés. Ne pas marcher à travers la matière déversée. Ne pas toucher les conteneurs endommagés ou la matière déversée sauf en cas de port de vêtements de protection appropriés. Ventiler les espaces clos.

Mesures d'urgence Aucune procédure d'urgence ne devrait s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations.

6.2 Précautions environnementales

Prévenir la pénétration dans les cours d'eau, les égouts, les sous-sols ou les endroits confinés.

6.3 Méthodes et matériaux de confinement et de nettoyage

Mesures de confinement/ nettoyage Pour les petits déversements, porter des gants et absorber la matière déversée avec une serviette en papier. Ne pas jeter la matière déversée dans les égouts.

6.4 Référence à d'autres sections

Voir la section 8 - Contrôles de l'exposition/protection individuelle, ainsi que la section 13 - Considérations de mise au rebut.

Section 7 : Manutention et stockage

7.1 Précautions pour une manutention sans danger

Manutention Aucune manipulation spéciale n'est nécessaire. Si une cartouche est percée, éviter tout contact avec les réactifs déversés. Éviter tout contact avec la peau et les yeux.

7.2 Conditions de sécurité du stockage, y compris toutes incompatibilités

Stockage Stocker conformément à l'étiquetage des produits. Tenir à l'écart des matières incompatibles. Garder sous clef. Conserver le conteneur/emballage hermétiquement fermé dans un endroit frais et bien aéré.

7.3 Utilisation(s) finale(s) spécifique(s)

Voir la section 1.2 - Utilisations pertinentes identifiées.

Section 8 : Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

Limites d'exposition/Lignes directrices		
	Résultat	**OSHA**
Glycérol (56-81-5)	TWA	15 mg/m3 TWA (brouillard, particules totales) ; 5 mg/m3 TWA (brouillard, fraction respirable)
Thiocyanate de guanidinium	TWA	5 mg/m3 TWA (sous forme de cyanure) *sous forme de composés du cyanure*

8.2 Contrôles d'exposition

Mesures/contrôles techniques Une bonne ventilation générale doit être utilisée. Les débits de ventilation doivent être adaptés aux conditions. Le cas échéant, utiliser des enceintes d'isolement, une ventilation aspirante locale ou d'autres moyens techniques pour maintenir les concentrations atmosphériques en dessous des limites d'exposition recommandées. Si les limites d'exposition n'ont pas été établies, maintenir les concentrations atmosphériques à un niveau acceptable.

Équipement de protection individuelle

Respiratoire Suivre les réglementations de l'OSHA relatives aux appareils respiratoires définies dans 29 CFR 1910.134 ou la norme européenne EN 149. Utiliser un appareil respiratoire approuvé par le NIOSH/MSHA ou la norme européenne EN 149 si les limites d'exposition sont dépassées ou des symptômes apparaissent.

Yeux/visage Porter des lunettes anti-éclaboussures contre les produits chimiques.

Peau/corps Porter des vêtements de protection

Contrôle d'exposition lié à la protection de l'environnement Suivre les bonnes pratiques pour la gestion de site et l'élimination des déchets.

Clef aux abréviations
OSHA = Administration de la sécurité et de la santé au travail
TWA = Les moyennes pondérées dans le temps sont basées sur des expositions de 8 h/jour, 40 h/semaine

Section 9 : Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques

Description de la matière			
Forme physique	Liquide	Apparence/Description	Les billes sont des composants solides blancs contenus dans des cartouches ; les réactifs sont des liquides limpides qui sont principalement tamponnés dans des solutions aqueuses. Les composants sont inodores.
Couleur	Blanc/transparent	Odeur	Inodore
Seuil d'odeur	Manque de données		
Propriétés générales			
Point d'ébullition	100 °C (212 °F)	Point de fusion/Point de congélation	0 °C (32 °F)
Température de décomposition	Manque de données	pH	7 à 9 Réactif de lyse n° 1 (TCG pH (3,7-4,1)) Réactif de lyse n° 2 (hydroxyde de sodium < 1 % pH 14).
Densité spécifique/relative	Manque de données	Solubilité dans l'eau	Manque de données
Viscosité	Manque de données	Propriétés explosives	Manque de données
Propriétés comburantes :	Manque de données		
Volatilité			
Pression de vapeur	Manque de données	Densité de vapeur	Manque de données
Taux d'évaporation	Manque de données		
Inflammabilité			
Point d'éclair	182,2222 à 293,3333 °C (360 à 560 °F) (réactif de liaison)	LSE	Manque de données
LIE	Manque de données	Auto-inflammation	Manque de données
Inflammabilité (solide, gaz)	Manque de données		
Environnemental(e)			
Coefficient de partage octanol/eau	Manque de données		

9.2 Autres informations

Aucun paramètre physique ou chimique supplémentaire noté.

Section 10 : Stabilité et réactivité

10.1 Réactivité

Pas de réactions dangereuses connues dans des conditions normales d'utilisation.

10.2 Stabilité chimique

Stable

10.3 Possibilité de réactions dangereuses

Il ne se produira pas de polymérisation dangereuse.

10.4 Situations à éviter

Matières incompatibles. La chaleur, le contact avec les acides ou l'eau de Javel peut entraîner le dégagement de gaz très toxiques.

10.5 Substances incompatibles

Acides, agents oxydants.

10.6 Produits de décomposition dangereux

Oxydes de carbone, oxydes de sodium.

Section 11 : Information toxicologique

11.1 Informations sur les effets toxiques

Composants		
Thiocyanate de guanidinium (5 % À 10 %)	593-84-0	**Toxicité aiguë :** Voie intrapéritonéale-Souris DL50 • 300 mg/kg
Glycérol (1 % À 5 %)	56-81-5	**Toxicité aiguë :** Ingestion/voie orale-Rat DL50 • 12 600 mg/kg ; *Comportement* : **Anesthésique général** ; *Comportement* : **Faiblesse musculaire** ; *Foie* ; **Autres changements** ; **Irritation :** Œil-Lapin • 500 mg, 24 heures • Légère irritation ; Peau-Lapin • 500 mg, 24 heures • Légère irritation ; **Toxicité de plusieurs doses :** Ingestion/voie orale-Souris DTmin • 560 g/kg, 8 semaines en continu ; *Poumons, thorax ou respiration* : **Changement structurel ou fonctionnel dans la trachée ou les bronches** ; Ingestion/voie orale-Souris DTmin • 2 800 mg/kg, 25 semaines en continu ; *Peau et appendices : Autre* : **Tumeurs** ; *Tumorigène* : **Facilite l'action d'agents cancérigènes connus** ; **Mutagène :** Analyse cytogénétique • Ingestion/voie orale-Rat • 1 g/kg ; Inhibition de l'ADN • Voie non définie-Homme • Lymphocyte (cellules somatiques) • 200 mmol/L ; **Reproduction :** Ingestion/voie orale-Rat DTmin • 100 mg/kg (mâle de 1 jour) ; *Effets sur la reproduction : Effets sur la fertilité* : **Mortalité après implantation** ; **Tumorigène/Cancérigène :** Ingestion/voie orale-Souris DTmin • 87,5 g/kg, 25 semaines par intermittence ; *Tumorigène* : **Agent tumorigène équivoque selon les critères RTECS** ; *Poumons, thorax ou respiration* : **Tumeurs** ; *Tumorigène* : **Facilite l'action d'agents cancérigènes connus**

Propriétés SGH	Classification
Toxicité aiguë	**EU/CLP**•Manque de données **SGH ONU**•Toxicité aiguë - voie orale 5 - ETAmix (voie orale) = 5 000 mg/kg **OSHA HCS 2012**•Manque de données
Corrosion/irritation cutanée	**EU/CLP**•Manque de données **SGH ONU**•Légère irritation cutanée 3 **OSHA HCS 2012**•Manque de données
Lésion/irritation grave des yeux	**EU/CLP**•Manque de données **SGH ONU**•Irritation oculaire 2 **OSHA HCS 2012**•Irritation oculaire 2
Sensibilisation cutanée	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Sensibilisation respiratoire	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Danger d'aspiration	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Cancérogénicité	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données

Propriétés SGH	Classification
Mutagénicité de cellule germinale	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
Toxicité pour la reproduction	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-SE	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-RE	**EU/CLP**•Manque de données **SGH ONU**•Manque de données **OSHA HCS 2012**•Manque de données

Effets éventuels sur la santé

Inhalation
Aigu (immédiat) Peut provoquer une irritation.
Chronique (différé) Aucune donnée disponible
Peau
Aigu (immédiat) Provoque une légère irritation cutanée.
Chronique (différé) Aucune donnée disponible
Yeux
Aigu (immédiat) Provoque une sévère irritation des yeux.
Chronique (différé) Aucune donnée disponible
Ingestion
Aigu (immédiat) Peut être nocif en cas d'ingestion.
Chronique (différé) Aucune donnée disponible

Clef aux abréviations
DL = Dose léthale
DT = Dose toxique

Section 12 : Information écologique

12.1 Toxicité

Le thiocyanate de guanidinium est toxique pour les organismes aquatiques.

12.2 Persistance et dégradabilité

Manque de données matérielles.

12.3 Potentiel bioaccumulatif

Manque de données matérielles.

12.4 Mobilité dans le sol

Manque de données matérielles.

12.5 Résultats des évaluations PBT et vPvB

Aucune évaluation PBT ou vPvB n'a été réalisée.

12.6 Autres effets nocifs

Aucune étude n'a été trouvée.

Section 13 : Considérations de mise au rebut

13.1 Méthodes de traitement des déchets

Déchets du produit Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

Conditionnement des déchets Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

13.2 Autres informations

Les échantillons biologiques, y compris les cartouches utilisées, doivent être traités comme s'ils étaient susceptibles de transmettre des agents infectieux. Consulter le personnel chargé des déchets environnementaux auprès de l'établissement pour les consignes concernant l'élimination correcte des cartouches usagées et des réactifs inutilisés. Ce produit peut présenter les caractéristiques des déchets dangereux couverts par la loi fédérale américaine de l'EPA sur la conservation et la remise en état des ressources (Resource Conservation and Recovery Act, RCRA) contenant des exigences d'élimination spécifiques. Consulter les réglementations locales et régionales car elles peuvent différer des réglementations nationales. Les établissements en dehors des États-Unis doivent vérifier les exigences de leur pays en matière d'élimination des déchets dangereux.

Section 14 : Informations de transport

	14.1 Numéro ONU	14.2 Nom d'expédition des Nations Unies	14.3 Classe(s) de danger pour le transport	14.4 Groupe d'emballage	14.5 Dangers pour l'environnement
DOT	ADD	Non régulé	ADD	ADD	ADD
TDG	ADD	Non régulé	ADD	ADD	ADD
IMO/IMDG	ADD	Non régulé	ADD	ADD	ADD
IATA/ICAO	ADD	Non régulé	ADD	ADD	ADD

14.6 Précautions spéciales pour l'utilisateur

Rien de précisé.

14.7 Transport en vrac conformément à l'annexe II de la convention MARPOL 73/78 et au code IBC

Manque de données.

Section 15 : Informations réglementaires

15.1 Réglementation relative à la sécurité, la santé et l'environnement/législation spécifique à la substance ou au mélange

Classifications de dangers SARA Aigu, incendie

Inventaire						
Composant	**CAS**	**LIS du Canada**	**LES du Canada**	**UE EINECS**	**UE ELNICS**	**TSCA**
Glycérol	56-81-5	Oui	Non	Oui	Non	Oui
Thiocyanate de guanidinium	593-84-0	Oui	Non	Oui	Non	Oui

Canada

Travail

Canada - SIMDUT - Classifications des substances

•Glycérol	56-81-5	Produit non contrôlé selon les critères de classification du SIMDUT
•Thiocyanate de guanidinium	593-84-0	Non énuméré

Canada - SIMDUT - Liste de divulgation des ingrédients

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

Environnement

Canada - LCPE - Liste des substances prioritaires

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

États-Unis

Travail

É.-U. - OSHA - Gestion de la sécurité des procédés - Produits chimiques très dangereux

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - OSHA - Produits chimiques spécifiquement réglementés

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

Environnement

É.-U. - CAA (Clean Air Act) - 1990 Polluants atmosphériques dangereux

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Substances dangereuses et leurs quantités à déclarer

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Radionucléides et leurs quantités à déclarer

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses QR EPCRA

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses TPQ

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Rapports sur les émissions

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Liste des produits chimiques PBT

•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

États-Unis – Californie

Environnement

É.-U. - Californie - Proposition 65 - Liste des substances cancérigènes		
•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour le développement		
•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Doses maximales admissibles (MADL)		
•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Niveaux de risque non significatifs (NSRL)		
•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Femme		
•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Homme		
•Glycérol	56-81-5	Non énuméré
•Thiocyanate de guanidinium	593-84-0	Non énuméré

15.2 Évaluation de sécurité chimique

Aucune évaluation de sécurité chimique n'a été effectuée.

Section 16 : Autres informations

Phrases pertinentes (code et texte entier)

H302 - Nocif en cas d'ingestion
H412 - Nocif pour la vie aquatique avec des effets durables
EUH031 - Au contact d'un acide, dégage un gaz toxique.

Déclaration de non-responsabilité

Les informations ci-dessus reposent sur les données dont nous disposons et que nous jugeons correctes. Dans la mesure où ces informations peuvent être utilisées dans des conditions hors de notre contrôle et que nous ne connaissons pas nécessairement, nous n'assumons aucune responsabilité pour les conséquences de leur utilisation et toutes les personnes recevant le produit doivent en déterminer personnellement les effets, les propriétés, ainsi que les mesures de protection et d'élimination nécessaires en rapport avec leurs conditions d'utilisation particulières. Aucune représentation, garantie ou assurance, explicite ou implicite (y compris une garantie d'aptitude ou de qualité marchande pour un but particulier) n'est faite concernant les produits, l'exactitude des informations, les résultats découlant de leur utilisation ou les risques liés à l'utilisation du produit. Il y a lieu de faire preuve de prudence lors de la manipulation et de l'utilisation du produit. Les informations ci-dessus sont fournies en toute bonne foi et avec la conviction qu'elles sont exactes. À la date de publication, nous fournissons toutes les informations pertinentes pour la manipulation prévisible du produit. Cependant, dans l'éventualité d'un incident indésirable associé à l'utilisation de ce produit, cette fiche de données de sécurité ne peut pas (et n'est pas conçue pour) se substituer à l'avis d'un personnel correctement formé.

Clef aux abréviations
ADD = Pas de données disponibles

Sicherheitsdatenblatt *Xpert Trichomonas*
Datum des Inkrafttretens: September 2016
Ersetzt (Datum): November 2015

Abschnitt 1: Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktname **Xpert Trichomonas**
Produktcode 900-0657; GXTV-10; GXTV-CE-10

1.2 Relevante identifizierte Verwendungen der Substanz oder Mischung und Verwendungen, von denen abgeraten wird

Relevante identifizierte Verwendung(en) Laborgebrauch

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Vereinigte Staaten
www.cepheid.com
USA: techsupport@cepheid.com
Telefon (Zentrale) 1 (888) 838-3222 - USA, Option 2
Telefon (Zentrale) 1 (408) 541-4191 - außerhalb der USA

1.4 Notrufnummer

Hersteller 1 (800) 424-9300 - CHEMTREC - 24-Stunden-Notruf
Hersteller 1 (703) 741-5500 - außerhalb der USA

Abschnitt 2: Mögliche Gefahren

EU/EWG
Nach: Verordnung (EG) Nr. 1272/2008 (CLP)/REACH 1907/2006 [geändert durch 453/2010]

2.1 Einstufung des Stoffs oder Gemischs

CLP Das folgende SDB gilt für das Fertigprodukt nur, wenn es im Labor benutzt wird. Es enthält flüssige Komponenten, von denen einige als gefriergetrocknetes Pulver und in Form von Reagenzien vorliegen, die in der Kartusche und in einer Nalgenflasche vorhanden sind. Alle Reagenzien sind klare, farblose Flüssigkeiten. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Nicht klassifiziert

2.2 Kennzeichnungselemente

CLP

Gefahrenhinweise Kein(e) Beschriftungselement(e) erforderlich

2.3 Sonstige Gefahren

CLP Nach Verordnung (EG) Nr. 1272/2008 (CLP) gilt dieses Material nicht als gefährlich.

UN GHS

Nach: Global harmonisiertes System der Einstufung und Kennzeichnung von Chemikalien (GHS) der UN

2.1 Einstufung des Stoffs oder Gemischs

UN GHS

Akute Toxizität, oral 5
Leichte Hautreizung 3
Augenreizung 2

2.2 Kennzeichnungselemente

UN GHS

WARNHINWEIS

Gefahrenhinweise

Möglicherweise gesundheitsschädlich bei Verschlucken
Verursacht leichte Hautreizungen
Verursacht schwere Augenreizung

Sicherheitshinweise

Vorbeugung

Nach Gebrauch gründlich waschen.
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

Reaktion

Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen.
Bei Hautreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen.
Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

2.3 Sonstige Gefahren

UN GHS

Nach dem global harmonisierten System zur Einstufung und Kennzeichnung (GHS) gilt dieses Produkt als gefährlich.

Vereinigte Staaten (VS)

Nach: OSHA 29 CFR 1910.1200 HCS

2.1 Einstufung des Stoffs oder Gemischs

OSHA HCS 2012

Augenreizung 2

2.2 Kennzeichnungselemente

OSHA HCS 2012

WARNHINWEIS

Gefahrenhinweise

Verursacht schwere Augenreizung

Sicherheitshinweise

Vorbeugung

Nach Gebrauch gründlich waschen.
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

Reaktion BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

2.3 Sonstige Gefahren

OSHA HCS 2012 Nach den Vorschriften der USA (29 CFR 1910.1200 - Norm für Gefahrenkommunikation) gilt dieses Produkt als gefährlich.

Kanada
Nach: WHMIS

2.1 Einstufung des Stoffs oder Gemischs

WHMIS Sonstige Giftwirkungen - D2B

2.2 Kennzeichnungselemente

WHMIS

Sonstige Giftwirkungen - D2B

2.3 Sonstige Gefahren

WHMIS In Kanada ist das oben genannte Produkt nach dem Workplace Hazardous Materials Information System (WHMIS) als gefährlich eingestuft.

2.4 Sonstige Angaben

Das folgende SDB gilt für das Fertigprodukt nur, wenn es im Labor oder klinischen Umfeld benutzt wird. Dieses Produkt ist eine Kartusche, in der flüssige Reagenzien und gefriergetrocknete Pulver enthalten sind. Die angegebenen Gefahren beziehen sich auf die in der Kartusche enthaltenen Reagenzien. Ein Kontakt mit den Reagenzien in dieser Kartusche ist im normalen Gebrauch nicht zu erwarten.

Abschnitt 3: Zusammensetzung/Angaben zu den Bestandteilen

3.1 Stoffe

Material erfüllt nicht die Kriterien einer Substanz.

3.2 Gemische

Zusammensetzung					
Chemische Bezeichnung	**Kennzeichnung**	**%**	**LD50/LC50**	**Klassifizierungen nach der Verordnung/Richtlinie**	**Bemerkungen**
Guanidiniumthiocyanat	**CAS:** 593-84-0 **EINECS:** 209-812-1	5% BIS 10%	KDV	**UN GHS:** Akute Tox. 4 (Verschlucken); Hautreizungen 3; Augenreizung 2B; Aquatisch Akut 3; Aquatisch Chronisch 3 **EU CLP:** Akute Tox. 4, H302; EUH031; Aquatisch Chronisch 3, H412 **OSHA HCS 2012:** Akute Tox. 4 (Verschlucken); Augenreizung 2B	KDV
Glycerol	**CAS:** 56-81-5 **EG-Nummer:** 200-289-5	1% BIS 5%	Verschlucken/oral-Ratte LD50 • 12.600 mg/kg	**UN GHS:** Augenreizung 2; Hautreizungen 3 **EU CLP:** Augenreizung 2, H319 **OSHA HCS 2012:** Augenreizung 2	KDV

Vollständiger Text der H-Hinweise siehe Abschnitt 16.

Abschnitt 4: Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Einatmen Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Verunfallten an die frische Luft bringen. Bei Atemschwierigkeiten Sauerstoffzufuhr einleiten. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat; künstliche Beatmung mit einer mit Einwegventil ausgestatteten Taschen-Sauerstoffmaske oder sonstigem geeigneten medizinischen Beatmungsgerät einleiten. Bei Atemstillstand künstliche Beatmung umgehend einleiten.

Haut Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei geringem Hautkontakt Material nicht auf andere Hautbereiche verteilen. Im Falle eines Hautkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Verunreinigte Kleidung entfernen und isolieren.

Augen Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Im Falle eines Augenkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Verschlucken Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei Einnahme Mund mit Wasser ausspülen (nur, wenn die Person bei Bewusstsein ist). KEIN Erbrechen herbeiführen. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat. Bei Einnahme sofort Arzt zu Rate ziehen.

4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen

Siehe Abschnitt 11 - Toxikologische Angaben.

4.3 Hinweis auf ärztliche Soforthilfe oder Spezialbehandlung

Hinweise für den Arzt Alle Behandlungsmaßnahmen sollten auf den beobachteten Anzeichen und Symptomen von Erschöpfung beim Patienten basieren. Außerdem ist zu berücksichtigen, dass es möglicherweise zum Kontakt mit anderen Materialien zusätzlich zu diesem Produkt kam.

Abschnitt 5: Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel	GROSSBRAND: Trockenlöschmittel, CO2, alkoholresistenter Schaum oder Wasserstrahl. KLEINBRAND: Trockenlöschmittel, CO2 oder Wasserstrahl.
Ungeeignete Löschmittel	Keine Daten verfügbar

5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren

Ungewöhnliche Brand-und Explosionsgefahren	Kann zur Bildung giftiger Kohlenoxid-, Schwefeloxid- und Stickstoffoxiddämpfe führen.
Gefährliche Verbrennungsprodukte	Keine Daten verfügbar

5.3 Hinweise für die Brandbekämpfung

Für die Feuerbekämpfung vorgesehene Standardarbeitsschutzbekleidung bietet einen begrenzten Schutz NUR in Brandfällen; sie ist ineffektiv bei Verschüttungen, wo ein direkter Kontakt mit dem Stoff möglich ist.
Chemikalienschutzbekleidung tragen, die speziell vom Hersteller empfohlen wird. Sie kann wenig oder keinen Thermoschutz bieten.
Umgebungsluftunabhängiges Atemschutzgerät (SCBA) für Überdruckbetrieb tragen.
KLEINBRAND: Behälter aus der Brandzone entfernen, wenn es kein Risiko darstellt.

Abschnitt 6: Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Persönliche Schutzmaßnahmen	Wenn eine Kartusche bricht, dann sind diese persönlichen Vorkehrungen anzuwenden. Entsprechende Schutzkleidung tragen. Nicht durch das verschüttete Material hindurch gehen. Beschädigte Behälter oder verschüttetes Material ohne geeignete Schutzkleidung nicht anfassen. Geschlossene Räume be- oder entlüften.
Sofortmaßnahmen	Es sind keine Notfallmaßnahmen erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird.

6.2 Umweltschutzmaßnahmen

Nicht in Gewässer, die Kanalisation, Keller oder enge Räume gelangen lassen.

6.3 Methoden und Material für Rückhaltung und Reinigung

Maßnahmen zur Rückhaltung/ Reinigung	Bei kleinen Verschüttungen Handschuhe tragen und Verschüttung mit einem Papiertuch aufnehmen. Verschüttetes Material nicht durch den Abfluss entsorgen.

6.4 Verweis auf andere Abschnitte

Siehe Abschnitt 8 - Einwirkungskontrolle/Personenschutz und Abschnitt 13 - Überlegungen zur Entsorgung.

Abschnitt 7: Handhabung und Lagerung

7.1 Schutzmaßnahmen zur sicheren Handhabung

Handhabung Keine spezielle Handhabung notwendig. Wenn eine Kartusche gebrochen ist, dann ist der Kontakt mit verschütteten Reagenzien zu vermeiden. Kontakt mit Haut und Augen vermeiden.

7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Umweltverträglichkeiten

Lagerung Produkt gemäß der Etikettierung lagern. Von nicht kompatiblem Material fernhalten. Unter Verschluss aufbewahren. Behälter/Verpackung dicht verschlossen an kühlem, gut belüftetem Ort lagern.

7.3 Spezifische Endanwendungen

Siehe Abschnitt 1.2 - Relevante identifizierte Nutzung.

Abschnitt 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstung

8.1 Zu überwachende Parameter

Expositionsgrenzwerte/Richtlinien		
	Ergebnis	**OSHA**
Glycerol (56-81-5)	zeitlich gewichtete Durchschnitte	15 mg/m3 TWA (Nebel, Gesamtpartikel); 5 mg/m3 TWA (Nebel, atembare Fraktion)
Guanidiniumthiocyanat	zeitlich gewichtete Durchschnitte	5 mg/m3 TWA (als CN) *als Cyanidverbindungen*

8.2 Begrenzung und Überwachung der Exposition

Technische Maßnahmen/ Kontrollen Es ist eine gute allgemeine Belüftung anzuwenden. Die Belüftungszahl sollte den Bedingungen entsprechen. Prozesskammern, lokale Abzugsanlage oder andere technische Kontrollmittel verwenden, um die Konzentration in der Luft unter den empfohlenen Grenzwerten zu halten. Wenn keine Grenzwerte festgelegt wurden, sind die Konzentrationen auf einem akzeptablen Niveau zu halten.

Persönliche Schutzausrüstung

Atemwege OSHA-Vorgaben für Atemschutzgeräte aus 29 CFR 1910.134 oder der Europäischen Norm EN 149 befolgen. Nach NIOSH/MSHA oder der Europäischen Norm EN 149 zugelassenes Atemschutzgerät benutzen, wenn die Grenzwerte überschritten werden oder Symptome auftreten.

Augen/Gesicht Schutzbrillen gegen Chemikalienspritzer tragen.

Haut/Körper Schutzkleidung tragen.

Umweltkontrollmaßnahmen Beste Praktiken bei Bauleitung und Abfallentsorgung anwenden.

Schlüssel für Abkürzungen
OSHA = Agentur für Sicherheit und Gesundheitsschutz am Arbeitsplatz
TWA = Zeitlich gewichtete Mittelwerte basieren auf einer Exposition von 8 Stunden/Tag, 40 Stunden/Woche

Abschnitt 9: Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Materialbeschreibung			
Physische Gestalt	Flüssigkeit	Aussehen/Beschreibung	Die Kügelchen sind feste weiße Bestandteile in Kartuschen; Reagenzien sind klare, in wässriger Lösung primär gepufferte Flüssigkeiten. Die Bestandteile sind geruchlos.
Farbe	Weiß/klar	Geruch	Geruchlos
Geruchsschwelle	Fehlende Daten		
Allgemeine Eigenschaften			
Siedepunkt	100 °C (212 °F)	Schmelzpunkt/Gefrierpunkt	0 °C (32 °F)
Zersetzungstemperatur	Fehlende Daten	pH	7 bis 9 Lysereagenz Nr. 1 (GTC, pH 3,7-4,1). Lysereagenz Nr. 2 (Natriumhydroxid, <1%, pH 14).
Spezifisches Gewicht/ Relative Dichte	Fehlende Daten	Wasserlöslichkeit	Fehlende Daten
Viskosität	Fehlende Daten	Explosive Eigenschaften	Fehlende Daten
Oxidationseigenschaften:	Fehlende Daten		
Volatilität			
Dampfdruck	Fehlende Daten	Dampfdichte	Fehlende Daten
Verdunstungsrate	Fehlende Daten		
Entflammbarkeit			
Flammpunkt	360 bis 560 °F (182,2222 bis 293,3333 °C) (Bindungsreagenz)	Obere Expositionsgrenze	Fehlende Daten
Untere Expositionsgrenze	Fehlende Daten	Selbstzündung	Fehlende Daten
Entflammbarkeit (Feststoff, Gas)	Fehlende Daten		
Umwelt			
Oktanol/Wasser-Verteilungskoeffizient	Fehlende Daten		

9.2 Sonstige Angaben

Keine zusätzlichen physikalischen und chemischen Parameter vermerkt.

Abschnitt 10: Stabilität und Reaktivität

10.1 Reaktivität

Keine gefährliche Reaktion bekannt unter Bedingungen der normalen Verwendung.

10.2 Chemische Stabilität

Stabil

10.3 Möglichkeit gefährlicher Reaktionen

Eine gefährliche Polymerisierung findet nicht statt.

10.4 Zu vermeidende Bedingungen

Inkompatibles Material. Wärme, Kontakt mit Säure oder Bleiche kann sehr giftige Gase freisetzen.

10.5 Inkompatible Materialien

Säuren, Oxidationsmittel.

10.6 Gefährliche Zersetzungsprodukte

Kohlenstoffoxide, Natriumoxide.

Abschnitt 11: Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

Bestandteile		
Guanidinthiocyanat (5% BIS 10%)	593-84-0	**Akute Toxizität:** Intraperitoneal-Maus LD50 • 300 mg/kg
Glycerol (1% BIS 5%)	56-81-5	**Akute Toxizität:** Verschlucken/oral-Ratte LD50 • 12.600 mg/kg; *Verhalten*: **Allgemein anästhetisch**; *Verhalten*: **Muskelschwäche**; *Leber*: **Andere Veränderungen**; **Reizung:** Auge-Kaninchen • 500 mg 24 Stunde(n) • Leichte Reizung; Haut-Kaninchen • 500 mg 24 Stunde(n) • Leichte Reizung; **Multidosis-Toxizität:** Verschlucken/oral-Maus TDLo • 560 g/kg 8 Woche(n)-Ständig; *Lungen, Thorax oder Atemwege*: **Strukturelle oder funktionale Veränderung bei Luftröhre oder Bronchien**; Verschlucken/oral-Maus TDLo • 2800 mg/kg 25 Woche(n)-Ständig; *Haut und ihre Adnexa: Andere*: **Tumore**; *Tumorauslösend*: **Erleichtert die Aktion eines bekannten Karzinogens**; **Mutagen:** Zytogenetische Analyse • Verschlucken/oral-Ratte • 1 g/kg; DNA-Hemmung • Undefiniert-Menschlich • Lymphozyt (somatische Zelle) • 200 mmol/l; **Reproduktion:** Verschlucken/oral-Ratte TDLo • 100 mg/kg (1 T. Männchen); *Wirkungen auf das Fortpflanzungssystem: Auswirkungen auf die Fruchtbarkeit*: **Postimplantationssterblichkeit**; **Tumorigen/Krebserzeugend:** Verschlucken/oral-Maus TDLo • 87,5 g/kg 25 Woche(n)-Zeitweise; *Tumorauslösend*: **Mehrdeutiger tumorerregender Wirkstoff nach RTECS-Kriterien**; *Lungen, Thorax oder Atemwege*: **Tumore**; *Tumorauslösend*: **Erleichtert die Aktion eines bekannten Karzinogens**

GHS-Eigenschaften	Klassifizierung
Akute Toxizität	**EU/CLP**•Fehlende Daten **UN GHS**•Akute Toxizität - oral 5 - ATEmix (oral) = 5000 mg/kg **OSHA HCS 2012**•Fehlende Daten
Hautätzende Wirkung/Reizung	**EU/CLP**•Fehlende Daten **UN GHS**•Leichte Hautreizung 3 **OSHA HCS 2012**•Fehlende Daten
Schwere Augenschäden/Augenreizung	**EU/CLP**•Fehlende Daten **UN GHS**•Augenreizung 2 **OSHA HCS 2012**•Augenreizung 2
Hautsensibilisierung	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Sensibilisierung der Atemwege	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Aspirationsgefahr	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Karzinogenität	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

GHS-Eigenschaften	Klassifizierung
Keimzell-Mutagenität	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Reproduktionstoxizität	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-SE	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-RE	**EU/CLP**•Fehlende Daten **UN GHS**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

Mögliche gesundheitliche Auswirkungen

Einatmen
Akut (sofort) Kann Reizung verursachen.
Chronisch (verzögert) Keine Daten verfügbar
Haut
Akut (sofort) Verursacht leichte Hautreizungen.
Chronisch (verzögert) Keine Daten verfügbar
Augen
Akut (sofort) Verursacht schwere Augenreizung.
Chronisch (verzögert) Keine Daten verfügbar
Verschlucken
Akut (sofort) Möglicherweise gesundheitsschädlich bei Verschlucken.
Chronisch (verzögert) Keine Daten verfügbar

Schlüssel für Abkürzungen
LD = Letale Dosis
TD = Toxische Dosis

Abschnitt 12: Umweltbezogene Angaben

12.1 Toxizität

Guanidiniumthiocyanat ist schädlich für Wasserorganismen.

12.2 Persistenz und Abbaubarkeit

Materialdaten fehlen.

12.3 Bioakkumulationspotenzial

Materialdaten fehlen.

12.4 Mobilität im Boden

Materialdaten fehlen.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Es wurde keine PBT- oder vPvB-Bewertung durchgeführt.

12.6 Andere schädliche Wirkungen

Es wurden keine Studien gefunden.

Abschnitt 13: Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Produktabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

Verpackungsabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

13.2 Sonstige Angaben

Bei biologischen Proben, einschließlich gebrauchter Kartuschen, ist davon auszugehen, dass sie Infektionserreger übertragen, und sie sind entsprechend zu behandeln. Konsultieren Sie das Personal für umweltgerechte Abfallentsorgung in Ihrer Institution für die ordnungsgemäße Entsorgung gebrauchter Kartuschen und unbenutzter Reagenzien. Dieser Stoff kann Eigenschaften von Sondermüll gemäß des in den USA geltenden EPA Resource Conservation and Recovery Act (RCRA) aufweisen und die Erfüllung spezieller Entsorgungsvorgaben erfordern. Prüfen Sie die bundesstaatlichen und lokalen Vorschriften daraufhin, wie sie sich von den bundesstaatlichen Entsorgungsvorschriften unterscheiden. Institutionen außerhalb der USA sollten die in ihrem Land geltenden Entsorgungsvorgaben für Sondermüll prüfen.

Abschnitt 14: Angaben zum Transport

	14.1 UN-Nummer	14.2 Korrekte UN-Bezeichnung des Frachtgutes	14.3 Transportgefahrenklasse(n)	14.4 Verpackungsgruppe	14.5 Umweltrisiken
DOT	KDV	Nicht reglementiert	KDV	KDV	KDV
TDG	KDV	Nicht reglementiert	KDV	KDV	KDV
IMO/IMDG	KDV	Nicht reglementiert	KDV	KDV	KDV
IATA/ICAO	KDV	Nicht reglementiert	KDV	KDV	KDV

14.6 Besondere Vorsichtsmaßnahmen für den Verwender

Keine Angaben.

14.7 Massengutbeförderung gemäß Anhang II des MARPOL-Übereinkommens 73/78 und gemäß IBC-Code

Fehlende Daten.

Abschnitt 15: Rechtsvorschriften

15.1 Vorschriften zur Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

SARA - Klassifizierung von Gefahren Akut, Brand

Inventar						
Bestandteil	**CAS**	**Kanada DSL**	**Kanada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Glycerol	56-81-5	Ja	Nein	Ja	Nein	Ja
Guanidiniumthiocyanat	593-84-0	Ja	Nein	Ja	Nein	Ja

Kanada

Arbeit

Kanada - WHMIS - Klassifizierung von Substanzen

•Glycerol	56-81-5	Nicht kontrolliertes Produkt gemäß den WHMIS-Einstufungskriterien
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Kanada - WHMIS - Kanadische Offenbarungsliste der Inhaltsstoffe (IDL)

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Umwelt

Kanada - CEPA - Liste prioritärer Stoffe

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten

Arbeit

USA - OSHA - Prozesssicherheitsmanagement - Hochgefährliche Chemikalien

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - OSHA - Speziell regulierte Chemikalien

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Umwelt

USA - CAA (Clean Air Act) - 1990 Gefährliche Schadstoffe in der Luft

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Gefährliche Stoffe und deren meldepflichtige Mengen

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Radionuklide und ihre berichtspflichtigen Mengen

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302: Äußerst gefährliche Stoffe EPCRA RQ-Werte

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302: Äußerst gefährliche Stoffe TPQ-Werte

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 - Emissionsmeldung

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 - Verzeichnis von PBT-Chemikalien

•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

Vereinigte Staaten - Kalifornien

Umwelt

Kalifornien - Proposition 65 - Liste der krebserzeugenden Stoffe		
•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet
Kalifornien - Proposition 65 - Entwicklungstoxizität		
•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet
Kalifornien - Proposition 65 - Maximal zulässige Dosierungen (MADL)		
•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet
Kalifornien - Proposition 65 - Ohne Nennenswerte Risiken (NSRL)		
•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet
Kalifornien - Proposition 65 - Weibliche Reproduktionstoxizität		
•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet
Kalifornien - Proposition 65 - Männliche Reproduktionstoxizität		
•Glycerol	56-81-5	Nicht gelistet
•Guanidiniumthiocyanat	593-84-0	Nicht gelistet

15.2 Stoffsicherheitsbeurteilung

Es wurde keine chemische Sicherheitsanalyse durchgeführt.

Abschnitt 16: Sonstige Angaben

Relevante Sätze (Code & Volltext)

H302 - Gesundheitsschädlich bei Verschlucken
H412 - Schädlich für Wasserorganismen, mit langfristiger Wirkung
EUH031 - Entwickelt bei Berührung mit Säure giftige Gase.

Haftungsausschluss/ Haftungshinweis

Die obigen Informationen basieren auf Daten, die uns verfügbar sind und die wir für korrekt halten. Da die Informationen unter Bedingungen angewendet werden können, die außerhalb unserer Kontrolle liegen und mit denen wir möglicherweise nicht vertraut sind, übernehmen wir keine Verantwortung für die Ergebnisse der Nutzung und alle Personen, die sie erhalten, müssen ihre eigenen Festlegungen bezüglich der Wirkungen, Eigenschaften, Schutzmaßnahmen und Entsorgung vornehmen, die zu den jeweiligen Bedingungen gehören. Es wird keine Zusicherung, Gewährleistung oder Garantie, weder in ausdrücklicher noch in implizierter Form (einschließlich einer Garantie für die Eignung oder Handelsüblichkeit), erteilt werden im Hinblick auf die Stoffe, die Genauigkeit dieser Informationen, die Ergebnisse, die aus deren Nutzung resultieren, oder die Gefahren, die mit der Nutzung des Stoffes verbunden sind. Bei der Handhabung und Nutzung des Stoffs ist Vorsicht anzuwenden. Die obigen Informationen wurden nach bestem Wissen angegeben und für akkurat gehalten. Zum Datum der Ausstellung bieten wir alle Informationen, die für die zu erwartende Handhabung des Stoffs relevant sind. Bei einem Vorfall mit diesem Produkt stellt dieses Sicherheitsdatenblatt keinen Ersatz für die Rücksprache mit entsprechend geschultem Personal dar und ist nicht dazu gedacht.

Schlüssel für Abkürzungen
KDV = Keine Daten verfügbar

Scheda dati di sicurezza *Xpert Trichomonas*

Data di decorrenza: Settembre 2016
Sostituisce la versione del: Novembre 2015

Sezione 1: Identificazione della sostanza/miscela e dell'azienda/impresa

1.1 Identificatore del prodotto

Nome prodotto **Xpert Trichomonas**
Codice prodotto 900-0657; GXTV-10; GXTV-CE-10

1.2 Usi pertinenti identificati della sostanza o della miscela e utilizzi sconsigliati

Usi pertinenti identificati Uso in laboratorio

1.3 Dettagli del fornitore della scheda dati di sicurezza

Produttore Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Stati Uniti
www.cepheid.com
USA: techsupport@cepheid.com
Telefono (generale) 1 (888) 838-3222 - USA Opzione 2
Telefono (generale) 1 (408) 541-4191 - Fuori dagli USA

1.4 Numero telefonico di emergenza

Produttore 1 (800) 424-9300 - CHEMTREC - Numero telefonico di emergenza attivo 24 ore su 24
Produttore 1 (703) 741-5500 - Fuori dagli USA

Sezione 2: Identificazione dei pericoli

UE/CEE

In ottemperanza a: Normativa (CE) n. 1272/2008 (CLP)/REACH 1907/2006 [emendata dalla 453/2010]

2.1 Classificazione della sostanza o della miscela

CLP La seguente Scheda informativa in materia di sicurezza (SDS) è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Contiene componenti liquidi, alcuni dei quali sono in polveri liofilizzate e reagenti che sono contenuti nella cartuccia e in una bottiglia Nalgene. Tutti i reagenti sono liquidi trasparenti e incolori. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Non classificato

2.2 Elementi dell'etichetta

CLP

Frasi di rischio Non è richiesta alcuna etichetta

2.3 Altri rischi

CLP In base al Regolamento (CE) n. 1272/2008 (CLP), questo materiale non è considerato pericoloso.

UN GHS

In ottemperanza a: Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN Globally Harmonized System of Classification and Labeling of Chemicals, GHS)

2.1 Classificazione della sostanza o della miscela

UN GHS

Tossicità acuta - per via orale 5
Lieve irritazione cutanea 3
Irritazione oculare 2

2.2 Elementi dell'etichetta

UN GHS

ATTENZIONE

Frasi di rischio

Può essere nocivo se ingerito
Provoca lieve irritazione cutanea
Provoca grave irritazione oculare

Frasi di prudenza

Prevenzione

Lavare accuratamente dopo l'uso.
Indossare guanti/indumenti protettivi/proteggere gli occhi/il viso.

Risposta

In caso di malessere, contattare un CENTRO ANTIVELENI o un medico.
In caso di irritazione della pelle: consultare un medico.
IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
Se l'irritazione degli occhi persiste: consultare un medico.

2.3 Altri rischi

UN GHS

In conformità al Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN GHS) questo prodotto è considerato pericoloso.

Stati Uniti (USA)

In ottemperanza a: OSHA 29 CFR 1910.1200 HCS

2.1 Classificazione della sostanza o della miscela

OSHA HCS 2012

Irritazione oculare 2

2.2 Elementi dell'etichetta

OSHA HCS 2012

ATTENZIONE

Frasi di rischio Provoca grave irritazione oculare.

Frasi di prudenza

Prevenzione Lavare accuratamente dopo l'uso.
Indossare guanti/indumenti protettivi/proteggere gli occhi/il viso.

Risposta IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
Se l'irritazione degli occhi persiste: consultare un medico.

2.3 Altri rischi

OSHA HCS 2012 Ai sensi della normativa statunitense (29 CFR 1910.1200 - Standard per la comunicazione dei pericoli), questo prodotto è considerato pericoloso.

Canada
In ottemperanza a: WHMIS

2.1 Classificazione della sostanza o della miscela

WHMIS Altri effetti tossici - D2B

2.2 Elementi dell'etichetta

WHMIS

Altri effetti tossici - D2B

2.3 Altri rischi

WHMIS In Canada, il prodotto di cui sopra è considerato pericoloso ai sensi del sistema di informazioni sui materiali pericolosi sul luogo di lavoro (Workplace Hazardous Materials Information System, WHMIS).

2.4 Altre informazioni

La seguente Scheda informativa in materia di sicurezza (SDS) è da considerarsi valida per il prodotto finito finale solo se usato in ambito clinico o di laboratorio. Questo prodotto è una cartuccia che contiene reagenti liquidi e polveri liofilizzate. I pericoli rappresentati fanno riferimento ai reagenti contenuti all'interno della cartuccia. Non è prevista alcuna esposizione ai reagenti all'interno della cartuccia durante il normale utilizzo.

Sezione 3: Composizione/Informazioni sugli ingredienti

3.1 Sostanze

Il materiale non soddisfa i criteri di classificazione come sostanza.

3.2 Miscele

Composizione					
Nome Chimico	**Identificatori**	**%**	**DL50/CL50**	**Classificazioni Secondo Regolamento/Direttiva**	**Commenti**
Guanidina tiocianato	**CAS:** 593-84-0 **EINECS:** 209-812-1	DAL 5% AL 10%	NDD	**UN GHS:** Toss. acuta 4 (orale); Irrit. cute 3; Irrit. occhi 2B; Acquatica acuta 3; Acquatica cronica 3 **UE CLP:** Toss. acuta 4, H302; EUH031; Acquatica cronica 3, H412 **OSHA HCS 2012:** Toss. acuta 4 (orale); Irrit. occhi 2B	NDD
Glicerolo	**CAS:** 56-81-5 **Numero CE:** 200-289-5	DAL 1% AL 5%	Effetti dell'ingestione/Orale-Ratto LD50 • 12600 mg/kg	**UN GHS:** Irrit. occhi 2; Irrit. cute 3 **UE CLP:** Irrit. occhi 2, H319 **OSHA HCS 2012:** Irrit. occhi 2	NDD

Per l'elenco completo delle frasi H, vedere la Sezione 16.

Sezione 4: Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Inalazione Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. Portare la persona colpita all'aria aperta. Somministrare ossigeno se la respirazione è difficile. Non usare il metodo bocca-a-bocca se la vittima ha inalato la sostanza; effettuare la respirazione artificiale con l'ausilio di una mascherina con valvola unidirezionale o altro dispositivo medico adeguato. Se la vittima non respira, effettuare la respirazione artificiale.

Cute Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di limitato contatto con la pelle, evitare la dispersione del materiale sulla pelle non interessata. In caso di contatto con la sostanza, sciacquare immediatamente la pelle con acqua corrente per almeno 20 minuti. Rimuovere e isolare gli indumenti contaminati.

Occhi Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di contatto con la sostanza, sciacquare immediatamente gli occhi con acqua corrente per almeno 20 minuti. Se l'irritazione degli occhi persiste: consultare un medico.

Ingestione Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di ingestione, sciacquare la bocca con acqua (solamente se l'infortunato è cosciente). NON provocare il vomito. Non usare il metodo bocca-a-bocca se la vittima ha ingerito la sostanza. In caso di ingestione consultare immediatamente un medico.

4.2 Sintomi ed effetti più importanti, acuti e ritardati

Consultare la Sezione 11 - Informazioni tossicologiche.

4.3 Indicazione delle attenzioni mediche immediate e dei trattamenti speciali necessari

Note per il medico Tutte le cure dovrebbero basarsi sull'osservazione di segni e sintomi di malessere nel paziente. Dovrebbe essere presa in considerazione la possibilità di sovraesposizione a materiali diversi da questo prodotto.

Sezione 5: Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione adeguati	INCENDI DI AMPIE DIMENSIONI: composto chimico secco, CO2, schiumogeno resistente all'alcol o getto d'acqua. INCENDI DI DIMENSIONI RIDOTTE: composto chimico secco, CO2 o getto d'acqua.
Mezzi di estinzione non adeguati	Nessun dato disponibile

5.2 Rischi speciali che scaturiscono dalla sostanza o dalla miscela

Rischi di esplosione e incendi inconsueti	Può emettere vapori tossici di ossidi di carbonio, ossidi di zolfo, ossidi di azoto.
Prodotti di combustione pericolosi	Nessun dato disponibile

5.3 Consiglio per i vigili del fuoco

Gli indumenti antincendio strutturali forniscono una protezione limitata SOLO in condizioni di incendio; non sono efficaci in condizioni di fuoriuscite in cui è probabile il contatto diretto con la sostanza.
Indossare abbigliamento protettivo contro gli agenti chimici specificatamente raccomandato dal produttore. Potrebbe fornire limitata o nessuna protezione termica.
Indossare un apparato di respirazione autonomo funzionante a pressione positiva (self-contained breathing apparatus, SCBA).
INCENDI DI DIMENSIONI RIDOTTE: spostare i contenitori dall'area colpita dall'incendio se non comporta alcun rischio.

Sezione 6: Misure contro il versamento accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure di emergenza

Precauzioni personali	Nel caso in cui si rompa una cartuccia, è possibile applicare queste precauzioni personali. Usare indumenti protettivi adatti. Non camminare sul materiale versato. Toccare i contenitori danneggiati o il materiale versato solo dopo aver indossato l'abbigliamento protettivo adeguato. Ventilare le aree chiuse.
Procedure di emergenza	Non si prevede la necessità di procedure di emergenza se il materiale viene utilizzato in condizioni normali come raccomandato.

6.2 Precauzioni ambientali

Evitare l'ingresso in corsi d'acqua, fognature, seminterrati o aree confinate.

6.3 Metodi e materiali per il contenimento e la pulizia

Misure di contenimento/ pulizia	Per piccole fuoriuscite, indossare guanti e assorbire la fuoriuscita con un tovagliolo di carta. Non gettare il materiale fuoriuscito nei tubi di scarico.

6.4 Riferimento ad altre sezioni

Consultare la Sezione 8 - Controlli dell'esposizione/Protezione personale e la Sezione 13 - Considerazioni per lo smaltimento.

Sezione 7: Manipolazione e stoccaggio

7.1 Precauzioni per la manipolazione sicura

Manipolazione Non è necessario nessun trattamento speciale. Nel caso in cui si rompa una cartuccia, evitare il contatto con i reagenti fuoriusciti. Evitare il contatto con gli occhi e con la pelle.

7.2 Condizioni per lo stoccaggio sicuro, incompatibilità eventuali incluse

Stoccaggio Conservare secondo le indicazioni presenti sull'etichetta del prodotto. Tenere lontano dai materiali incompatibili. Conservare sotto chiave. Conservare il recipiente/ contenitore ben chiuso in luogo fresco e ben ventilato.

7.3 Usi finali specifici

Consultare la Sezione 1.2 - Usi pertinenti identificati.

Sezione 8: Controlli di esposizione/Protezione personale

8.1 Parametri di controllo

Limiti di Esposizione/Linee Guida		
	Risultato	**OSHA**
Glicerolo (56-81-5)	TWA	15 mg/m3 TWA (nebbia, particolato totale); 5 mg/m3 TWA (nebbia, frazione respirabile)
Guanidina tiocianato	TWA	5 mg/m3 TWA (come CN) *come composti del cianuro*

8.2 Controlli di esposizione

Misure/Controlli tecnici Garantire una ventilazione generale adeguata. I regimi di ventilazione devono essere adeguati alle condizioni. Se applicabile, utilizzare camere di protezione dei processi, impianti di ventilazione locale o altri controlli tecnici per mantenere i livelli di contaminanti aerei al di sotto dei limiti di esposizione raccomandati. Qualora i limiti di esposizione non fossero stati stabiliti, mantenere i contaminanti aerei a un livello accettabile.

Dispositivi di protezione individuale

Respirazione Attenersi alle indicazioni del respiratore OSHA disponibili in 29 CFR 1910.134 o nella norma europea EN 149. In caso di superamento dei limiti di esposizione o manifestazione di sintomi, usare un respiratore approvato da NIOSH/MSHA o dalla norma europea EN 149.

Occhi/Volto Indossare occhiali protettivi per sostanze chimiche.

Pelle/Corpo Indossare indumenti protettivi.

Controlli dell'esposizione ambientale Seguire le migliori pratiche per la gestione del sito e per lo smaltimento dei rifiuti.

Legenda delle abbreviazioni
OSHA = Occupational Safety and Health Administration (Agenzia per la salute e la sicurezza sul lavoro)
TWA = Time-Weighted Averages (Medie pesate nel tempo) basate su esposizioni da 8 ore/giorno, 40 ore/settimana

Sezione 9: Proprietà chimico-fisiche

9.1 Informazioni sulle proprietà chimico-fisiche

Descrizione del materiale			
Forma fisica	Liquido	Aspetto/Descrizione	Le perline sono componenti solidi, di colore bianco, presenti nelle cartucce; i reagenti sono liquidi trasparenti che vengono stabilizzati principalmente in soluzioni acquose. I componenti sono inodori.
Colore	Bianco/trasparente	Odore	Inodore
Soglia di odore	Dati mancanti		
Proprietà generali			
Punto di ebollizione	100 °C (212 °F)	Punto di fusione/Punto di congelamento	0 °C (32 °F)
Temperatura di decomposizione	Dati mancanti	pH	Da 7 a 9 Reagente di lisi n. 1 (GTC pH 3,7-4,1). Reagente di lisi n. 2 (idrossido di sodio < 1% pH 14).
Gravità specifica/densità relativa	Dati mancanti	Solubilità in acqua	Dati mancanti
Viscosità	Dati mancanti	Proprietà esplosive	Dati mancanti
Proprietà ossidanti:	Dati mancanti		
Volatilità			
Pressione di vapore	Dati mancanti	Densità del vapore	Dati mancanti
Tasso di evaporazione	Dati mancanti		
Infiammabilità			
Punto di infiammabilità	Da 182,22 °C a 293,33 °C (da 360 °F a 560 °F) (Reagente legante)	UEL	Dati mancanti
LEL	Dati mancanti	Autoaccensione	Dati mancanti
Infiammabilità (solido, gas)	Dati mancanti		
Ambientali			
Coefficiente di ripartizione ottanolo-acqua	Dati mancanti		

9.2 Altre informazioni

Non sono state osservate altre proprietà chimico-fisiche.

Sezione 10: Stabilità e reattività

10.1 Reattività

Nessuna reazione pericolosa nota nelle normali condizioni di utilizzo.

10.2 Stabilità chimica

Stabile

10.3 Possibilità di reazioni pericolose

Non si verificherà polimerizzazione pericolosa.

10.4 Condizioni da evitare

Materiali incompatibili. Il calore, a contatto con acidi o candeggina, può liberare gas molto tossici.

10.5 Materiali incompatibili

Acidi, agenti ossidanti.

10.6 Prodotti di decomposizione pericolosi

Ossidi di carbonio, ossidi di sodio.

Sezione 11: Informazioni tossicologiche

11.1 Informazioni sugli effetti tossicologici

Componenti		
Guanidina tiocianato (DAL 5% AL 10%)	593-84-0	**Tossicità acuta:** Intraperitoneale-Topo LD50 • 300 mg/kg
Glicerolo (DAL 1% AL 5%)	56-81-5	**Tossicità acuta:** Ingestione/Orale-Ratto LD50 • 12600 mg/kg; *Comportamentale*: **Anestetico generale**; *Comportamentale*: **Astenia muscolare**; *Fegato*: **Altre alterazioni**; **Irritazione:** Occhio-Coniglio • 500 mg 24 ore • Lieve irritazione; Pelle-Coniglio • 500 mg 24 ore • Lieve irritazione; **Tossicità per dosi multiple:** Effetti dell'ingestione/Orale-Topo TDLo • 560 g/kg 8 settimane-continua; *Polmoni, torace o respirazione*: **Alterazione strutturale o funzionale della trachea o dei bronchi**; Effetti dell'ingestione/Orale-Topo TDLo • 2800 mg/kg 25 settimane-continua; *Cute e annessi cutanei: Altro*: **Tumori**; *Tumorigenico*: **Facilita l'azione di noti cancerogeni**; **Mutageno:** Analisi citogenetica • Effetti dell'ingestione/Orale-Ratto • 1 g/kg; Inibizione del DNA • Indefinito-Umano • Linfociti (cellule somatiche) • 200 mmol/L; **Riproduttiva:** Effetti dell'ingestione/Orale-Ratto TDLo • 100 mg/kg (1 G uomo); *Effetti sulla riproduzione: Effetti sulla fertilità*: **Mortalità post-impianto**; **Tumorigenico / Cancerogeno:** Effetti dell'ingestione/Orale-Topo TDLo • 87,5 g/kg 25 settimane-Intermittente; *Tumorigenico*: **Agente cancerogeno equivoco secondo i criteri RTECS**; *Polmoni, torace o respirazione*: **Tumori**; *Tumorigenico*: **Facilita l'azione di noti cancerogeni**

Proprietà GHS	Classificazione
Tossicità acuta	**UE/CLP**•Dati mancanti **UN GHS**•Tossicità acuta - Orale 5 - ATEmix (orale) = 5000 mg/kg **OSHA HCS 2012**•Dati mancanti
Corrosione/Irritazione cutanea	**UE/CLP**•Dati mancanti **UN GHS**•Lieve irritazione cutanea 3 **OSHA HCS 2012**•Dati mancanti
Grave irritazione/danno oculare	**UE/CLP**•Dati mancanti **UN GHS**•Irritazione oculare 2 **OSHA HCS 2012**•Irritazione oculare 2
Sensibilizzazione cutanea	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Sensibilizzazione respiratoria	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Pericolo derivante dall'inalazione	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Cancerogenicità	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti

Proprietà GHS	Classificazione
Mutagenesi delle cellule embrionali	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Tossicità per la riproduzione	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-SE	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-RE	**UE/CLP**•Dati mancanti **UN GHS**•Dati mancanti **OSHA HCS 2012**•Dati mancanti

Potenziali effetti sulla salute

Inalazione
Acuto (immediato) Può causare irritazione.
Cronico (ritardato) Nessun dato disponibile

Cute
Acuto (immediato) Provoca lieve irritazione cutanea.
Cronico (ritardato) Nessun dato disponibile

Occhi
Acuto (immediato) Provoca grave irritazione oculare.
Cronico (ritardato) Nessun dato disponibile

Ingestione
Acuto (immediato) Può essere nocivo se ingerito.
Cronico (ritardato) Nessun dato disponibile

Legenda delle abbreviazioni
DL = Dose letale
TD = Dose tossica

Sezione 12: Informazioni ecologiche

12.1 Tossicità

Il tiocianato di guanidinio è nocivo per gli organismi acquatici.

12.2 Persistenza e degradabilità

Dati materiale mancanti.

12.3 Potenziale di bioaccumulo

Dati materiale mancanti.

12.4 Mobilità nel suolo

Dati materiale mancanti.

12.5 Risultati della valutazione PBT e vPvB

Non sono state condotte valutazioni PBT e vPvB.

12.6 Altri effetti avversi

Non sono stati trovati studi.

Sezione 13: Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti del prodotto Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

Rifiuti di imballaggio Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

13.2 Altre informazioni

I campioni biologici, tra cui le cartucce esauste, devono essere trattati come materiale in grado di trasmettere agenti infettivi. Rivolgersi al personale addetto allo smaltimento dei rifiuti ambientali del proprio istituto per ottenere informazioni utili sul corretto smaltimento delle cartucce esauste e dei reagenti inutilizzati. Questo materiale può presentare caratteristiche dell'EPA Resource Conservation and Recovery Act (RCRA) sui residui pericolosi che richiedono uno smaltimento specifico. Verificare le normative nazionali e locali perché possono differire dalle normative regionali sullo smaltimento. Le istituzioni al di fuori degli Stati Uniti dovrebbero verificare i requisiti per lo smaltimento dei residui pericolosi del proprio Paese.

Sezione 14: Informazioni sul trasporto

	14.1 Numero ONU	14.2 Nome di spedizione corretto ONU	14.3 Classi di pericolosità per il trasporto	14.4 Gruppo di imballaggio	14.5 Pericoli ambientali
DOT	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD
TDG	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD
IMO/IMDG	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD
IATA/ICAO	NDD	Non soggetto a regolamentazione	NDD	NDD	NDD

14.6 Precauzioni speciali per l'utilizzatore

Nessuna specificata.

14.7 Trasporto alla rinfusa in base all'Allegato II della Convenzione MARPOL 73/78 e al Codice IBC

Dati mancanti.

Sezione 15: Informazioni regolatorie

15.1 Normative/legislazione in materia di ambiente, salute e sicurezza specifiche per la sostanza o la miscela

Classificazioni dei rischi SARA Acuta, incendio

Inventario						
Componente	**CAS**	**Canada DSL**	**Canada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Glicerolo	56-81-5	Sì	No	Sì	No	Sì
Guanidina tiocianato	593-84-0	Sì	No	Sì	No	Sì

Canada

Lavoro

Canada - WHMIS - Classificazione delle sostanze

•Glicerolo	56-81-5	Prodotto non controllato in base ai criteri di classificazione WHMIS
•Guanidina tiocianato	593-84-0	Non elencato

Canada - WHMIS - Elenco degli ingredienti

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

Ambiente

Canada - CEPA - Elenco sostanze prioritarie

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

Stati Uniti

Lavoro

USA - OSHA - Gestione dei processi di sicurezza - Sostanze chimiche estremamente pericolose

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

USA - OSHA - Prodotti chimici specificamente regolati

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

Ambiente

USA - CAA (Clean Air Act) - 1990 Inquinanti pericolosi per l'aria

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

USA - CERCLA/SARA - Sostanze pericolose e quantità riportabili

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

USA - CERCLA/SARA - Radionuclidi e quantità riportabili

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose EPCRA RQ

•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose TPQ		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - CERCLA/SARA - Sezione 313 - Rapporto sulle emissioni		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - CERCLA/SARA - Sezione 313 - Certificazione chimica PBT		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

Stati Uniti - California

Ambiente

USA - California - Proposta 65 - Elenco sostanze cancerogene		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - California - Proposta 65 - Tossicità dello sviluppo		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - California - Proposta 65 - MADL (Maximum Allowable Dose Levels, livelli di dose massimi consentiti)		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - California - Proposta 65 - NSRL (No Significant Risk Levels, nessun livello di rischio significativo)		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - California - Proposta 65 - Tossicità sulla riproduzione - Femminile		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato
USA - California - Proposta 65 - Tossicità sulla riproduzione - Maschile		
•Glicerolo	56-81-5	Non elencato
•Guanidina tiocianato	593-84-0	Non elencato

15.2 Valutazione della sicurezza chimica

Non è stata eseguita alcuna valutazione della sicurezza chimica.

Sezione 16: Altre informazioni

Frasi pertinenti (codice e testo completo)

H302 - Nocivo se ingerito.
H412 - Nocivo per gli organismi acquatici con effetti di lunga durata.
EUH031 - A contatto con acidi libera gas tossico.

Esclusione/Dichiarazione di responsabilità

Le suddette informazioni si basano su dati a nostra disposizione e ritenuti corretti. Poiché le informazioni possono essere applicate in condizioni che vanno oltre il nostro controllo e che potremmo non conoscere bene, non ci assumiamo nessuna responsabilità per i risultati derivanti dall'uso che ne viene fatto, e tutte le persone che ne usufruiranno devono stabilire gli effetti, le proprietà, le protezioni e lo smaltimento riguardanti ogni singola situazione. Nessuna rappresentazione, garanzia o assicurazione, esplicita o implicita (comprese una garanzia di idoneità o commerciabilità per un particolare scopo), viene fatta per quanto riguarda i materiali, la precisione delle informazioni fornite, i risultati ottenibili dall'uso che ne viene fatto, o i pericoli connessi con l'uso del materiale. L'uso e la manipolazione del materiale devono essere eseguiti con attenzione. Le suddette informazioni sono fornite in buona fede e con la convinzione che siano esatte. A partire dalla data di emissione, vengono fornite tutte le informazioni a disposizione relativamente al trattamento prevedibile del materiale. Tuttavia, in caso di un incidente avverso relativo al prodotto, questa Scheda informativa in materia di sicurezza non è, e non intende essere, il surrogato della consultazione con personale opportunamente addestrato.

Legenda delle abbreviazioni
NDD = Nessun dato disponibile

Ficha de datos de seguridad *Xpert Trichomonas*
Fecha de entrada en vigor: Septiembre de 2016
Sustituye a fecha: Noviembre de 2015

Sección 1: Identificación de la sustancia/mezcla y del proyecto/empresa

1.1 Identificador del producto

Nombre del producto **Xpert Trichomonas**
Código del producto 900-0657; GXTV-10; GXTV-CE-10

1.2 Usos identificados de la sustancia o mezcla y usos no recomendados

Usos identificados Uso en laboratorio

1.3 Detalles del proveedor de la ficha de datos de seguridad

Fabricante Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Estados Unidos
www.cepheid.com
EE. UU.: techsupport@cepheid.com
Teléfono (general) 1 (888) 838-3222 - EE. UU. (opción 2)
Teléfono (general) 1 (408) 541-4191 - Fuera de EE. UU.

1.4 Número de teléfono de emergencia

Fabricante 1 (800) 424-9300 - CHEMTREC - Emergencia (24 h)
Fabricante 1 (703) 741-5500 - Fuera de EE. UU.

Sección 2: Identificación de riesgos

UE/CEE

De acuerdo con: Reglamento (CE) Nº 1272/2008 (CLP)/REACH 1907/2006 [modificado por 453/2010]

2.1 Clasificación de la sustancia o mezcla

CLP La siguiente FDS está destinada exclusivamente al uso en laboratorio del producto final acabado. Contiene componentes líquidos, algunos de los cuales son reactivos y polvos liofilizados almacenados en el cartucho y en una botella Nalgene. Todos los reactivos son líquidos transparentes e incoloros. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)y(2).
No clasificado

2.2 Elementos de la etiqueta

CLP

Declaraciones de riesgo No se requieren elementos de etiquetado

2.3 Otros riesgos

CLP De acuerdo con el Reglamento (CE) Nº 1272/2008 (CLP), este material no se considera peligroso.

SGA de la ONU

De acuerdo con: Sistema Globalmente Armonizado (SGA) de Clasificación y Etiquetado de Productos Químicos de la ONU

2.1 Clasificación de la sustancia o mezcla

SGA de la ONU

Toxicidad oral aguda 5
Irritación cutánea leve 3
Irritación ocular 2

2.2 Elementos de la etiqueta

SGA de la ONU

ADVERTENCIA

Declaraciones de riesgo

Nocivo en caso de ingestión
Provoca irritación cutánea
Provoca irritación ocular grave

Declaraciones preventivas

Prevención

Lavarse concienzudamente tras la manipulación.
Llevar guantes/prendas/gafas/máscara de protección.

Respuesta

Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico en caso de malestar.
En caso de irritación cutánea: Consultar a un médico.
EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando.
Si persiste la irritación ocular: Consultar a un médico.

2.3 Otros riesgos

SGA de la ONU

De acuerdo con el Sistema Globalmente Armonizado de Clasificación y Etiquetado de Productos Químicos (SGA), este producto se considera peligroso.

Estados Unidos (EE. UU.)
De acuerdo con: OSHA 29 CFR 1910.1200 HCS

2.1 Clasificación de la sustancia o mezcla

HCS 2012 de la OSHA

Irritación ocular 2

2.2 Elementos de la etiqueta

HCS 2012 de la OSHA

ADVERTENCIA

Declaraciones de riesgo

Provoca irritación ocular grave.

Declaraciones preventivas

Prevención

Lavarse concienzudamente tras la manipulación.
Llevar guantes/prendas/gafas/máscara de protección.

Respuesta EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando.
Si persiste la irritación ocular: Consultar a un médico.

2.3 Otros riesgos

HCS 2012 de la OSHA De acuerdo con el reglamento de los Estados Unidos (29 CFR 1910.1200 - Estándar de Comunicación de Riesgos), este producto se considera peligroso.

Canadá
De acuerdo con: WHMIS

2.1 Clasificación de la sustancia o mezcla

WHMIS Otros efectos tóxicos - D2B

2.2 Elementos de la etiqueta

WHMIS

Otros efectos tóxicos - D2B

2.3 Otros riesgos

WHMIS El producto mencionado se considera peligroso en Canadá, de acuerdo con el Sistema de Información de Materiales Peligrosos en el Lugar de Trabajo (WHMIS).

2.4 Información adicional

La siguiente FDS está destinada exclusivamente al uso en laboratorio o el entorno clínico del producto final acabado. Este producto es un cartucho que contiene reactivos líquidos y polvos liofilizados. Los peligros representados se basan en los reactivos contenidos en el cartucho. No se espera ninguna exposición a los reactivos de este cartucho durante el uso normal.

Sección 3: Composición/información de los ingredientes

3.1 Sustancias

El material no cumple con los criterios de clasificación de sustancias.

3.2 Mezclas

Composición					
Nombre del producto químico	**Identificadores**	**%**	**LD50/LC50**	**Clasificaciones de acuerdo con el reglamento/directiva**	**Comentarios**
Tiocianato de guanidina	**CAS:** 593-84-0 **EINECS:** 209-812-1	5 % A 10 %	No hay datos disponibles	**SGA de la ONU:** Tox. aguda 4 (oral); Irrit. cutánea 3; Irrit. ocular 2B; Acuática aguda 3; Acuática crónica 3 **CLP UE:** Tox. aguda 4, H302; EUH031; Acuática crónica 3, H412 **HCS 2012 de la OSHA:** Tox. aguda 4 (oral); Irrit. ocular 2B	No hay datos disponibles
Glicerol	**CAS:** 56-81-5 **Numero CE:** 200-289-5	1 % A 5 %	Ingestión/Oral-Rata LD50 • 12600 mg/kg	**SGA de la ONU:** Irrit. ocular 2; Irrit. cutánea 3 **CLP UE:** Irrit. ocular 2, H319 **HCS 2012 de la OSHA:** Irrit. ocular 2	No hay datos disponibles

Acceda a la Sección 16 para consultar el texto completo de las declaraciones de riesgo.

Sección 4: Medidas de primeros auxilios

4.1 Descripción de las medidas de primeros auxilios

Inhalación No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Traslade a la persona al aire libre. Si la respiración resulta difícil, administre oxígeno. No utilice el método de boca a boca si la víctima ha inhalado la sustancia; proporcione respiración artificial con la ayuda de una máscara de bolsillo equipada con una válvula de una sola vía u otro dispositivo médico de respiración adecuado. Si la persona no respira, proporcione respiración artificial.

Piel No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Ante un contacto menor con la piel, evite la difusión del material sobre la piel no afectada. Si entra en contacto con la sustancia, enjuague inmediatamente la piel con agua durante al menos 20 minutos. Retire y aísle la ropa contaminada.

Ojo No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Si entra en contacto con la sustancia, enjuague inmediatamente los ojos con agua durante al menos 20 minutos. Si persiste la irritación ocular: Consultar a un médico.

Ingestión No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. En caso de ingestión, enjuague la boca con agua (solo si la persona está consciente). NO provoque el vómito. No utilice el método de boca a boca si la víctima ha ingerido la sustancia. En caso de ingestión, solicite atención médica inmediatamente.

4.2 Síntomas y efectos más importantes, tanto agudos como retardados

Consulte la Sección 11 - Información toxicológica.

4.3 Indicación de cualquier atención médica inmediata y tratamiento especial necesarios

Notas para el médico Todos los tratamientos deben basarse en señales y síntomas observados en el paciente. Considere si puede haberse producido una sobreexposición a otros materiales distintos de este producto.

Sección 5: Medidas antiincendios

5.1 Medios de extinción

Medios de extinción adecuados INCENDIOS MAYORES: Polvo químico seco, CO_2, espuma resistente al alcohol o agua pulverizada.
INCENDIOS MENORES: Polvo químico seco, CO_2 o agua pulverizada.

Medios de extinción inadecuados No hay datos disponibles

5.2 Riesgos especiales procedentes de la sustancia o mezcla

Riesgos de incendio y explosión inusuales Puede emitir vapores tóxicos de óxidos de carbono, óxidos de azufre y óxidos de nitrógeno.

Productos de combustión peligrosa No hay datos disponibles

5.3 Consejos para el personal antiincendios

El traje de protección estándar del personal antiincendios proporciona protección limitada EXCLUSIVAMENTE contra el fuego; no resulta efectivo ante vertidos donde es posible el contacto directo con la sustancia.
Utilice un traje de protección química específicamente recomendado por el fabricante. Puede proporcionar poca o ninguna protección térmica.
Utilice un equipo de respiración autónomo (ERA) de presión positiva.
INCENDIOS MENORES: Mueva los contenedores del área del incendio si la operación no conlleva riesgos.

Sección 6: Medidas en caso de liberación accidental

6.1 Precauciones personales, equipamiento protector y procedimientos de emergencia

Precauciones personales	En caso de romperse un cartucho, pueden aplicarse estas precauciones personales. Utilice un traje de protección adecuado. No camine a través del material vertido. No toque los contenedores dañados ni los materiales vertidos a menos que utilice un traje de protección adecuado. Ventile las áreas cerradas.
Procedimientos de emergencia	Se espera que no sea necesario aplicar procedimientos de emergencia si el material se utiliza bajo condiciones normales y del modo recomendado.

6.2 Precauciones medioambientales

Evite la entrada en alcantarillas, vías fluviales, sótanos y espacios cerrados.

6.3 Métodos y materiales de contención y limpieza

Medidas de contención/ limpieza	Para vertidos menores, utilice guantes y absorba el vertido con una toalla de papel. No deseche materiales vertidos por el desagüe.

6.4 Referencia a otras secciones

Consulte la Sección 8 - Controles de exposición/protección personal y la Sección 13 - Consideraciones de eliminación.

Sección 7: Manipulación y almacenamiento

7.1 Precauciones para la manipulación segura

Manipulación	No se necesita ninguna manipulación especial. En caso de romperse un cartucho, evite el contacto con los reactivos vertidos. Evite el contacto con la piel y los ojos.

7.2 Condiciones para el almacenamiento seguro, incluidas posibles incompatibilidades

Almacenamiento	Almacénelos de acuerdo con las indicaciones de su etiqueta. Mantenga el producto alejado de materiales incompatibles. Guardar bajo llave. Mantenga el contenedor/embalaje bien cerrado en un lugar fresco y ventilado.

7.3 Usos finales específicos

Consulte la Sección 1.2 - Usos identificados relevantes.

Sección 8: Controles de exposición/protección personal

8.1 Parámetros de control

Directrices/límites de exposición		
	Resultado	**OSHA**
Glicerol (56-81-5)	TWAs	15 mg/m3 TWA (neblina, partículas totales); 5 mg/m3 TWA (neblina, fracción respirable)
Tiocianato de guanidina	TWAs	5 mg/m3 TWA (como CN) *como compuestos de cianuro*

8.2 Controles de exposición

Controles/medidas de ingeniería Es necesaria una buena ventilación general. La tasa de ventilación debe corresponder a las condiciones. Si es posible, utilice recintos de procesamiento, ventilación local u otros controles de ingeniería para mantener los niveles del aire por debajo de los límites de exposición recomendados. Si los límites de exposición no se han establecido, mantenga los niveles del aire a un nivel aceptable.

Equipo de protección individual

Respiratorios Siga los reglamentos para máscaras de la OSHA incluidas en el estándar 29 CFR 1910.134 y en el estándar europeo EN 149. Utilice una máscara aprobada por la NIOSH/MSHA o la norma europea EN 149 si se superan los límites de exposición o se experimentan síntomas.

Ocular/facial Utilice gafas de protección contra salpicaduras químicas.

Piel/cuerpo Utilice un traje de protección

Controles de exposición en el medio ambiente Siga las buenas prácticas para administrar el centro y eliminar residuos.

Clave de abreviaturas
OSHA = Administración de Seguridad y Salud Ocupacional
TWA = Los promedios de tiempo ponderado se basan en exposiciones durante 8 h/día y 40 h/semana

Sección 9: Propiedades físicas y químicas

9.1 Información sobre las propiedades físicas y químicas

Descripción del material			
Forma física	Líquido	Aspecto/Descripción	Las microesferas son componentes sólidos blancos en cartuchos; los reactivos son líquidos transparentes, principalmente diluidos en soluciones acuosas. Los componentes son inodoros.
Color	Blanco/transparente	Olor	Inodoro
Umbral de olor	Faltan datos		
Propiedades generales			
Punto de ebullición	100 °C (212 °F)	Punto de fusión/punto de congelación	0 °C (32 °F)
Temperatura de descomposición	Faltan datos	pH	7 a 9 Reactivo de lisis nº 1 (GTC pH (3,7-4,1.)) Reactivo de lisis nº 2 (hidróxido sódico <1 % pH 14).
Gravedad específica/densidad relativa	Faltan datos	Hidrosolubilidad	Faltan datos
Viscosidad	Faltan datos	Propiedades explosivas	Faltan datos
Propiedades oxidantes:	Faltan datos		
Volatilidad			
Presión del vapor	Faltan datos	Densidad del vapor	Faltan datos
Tasa de evaporación	Faltan datos		
Inflamabilidad			
Punto de inflamación	360 a 560 °F (182,2222 a 293,3333 °C) (Reactivo de unión)	UEL	Faltan datos
LEL	Faltan datos	Autoignición	Faltan datos
Inflamabilidad (sólido, gas)	Faltan datos		
Medioambiental			
Coeficiente de reparto octanol/agua	Faltan datos		

9.2 Información adicional

No se han anotado parámetros físicos o químicos adicionales.

Sección 10: Estabilidad y reactividad

10.1 Reactividad

No se conocen reacciones peligrosas bajo condiciones normales de uso.

10.2 Estabilidad del producto químico

Estable

10.3 Posibilidad de reacciones peligrosas

No ocurrirá polimerización peligrosa.

10.4 Condiciones que se deben evitar

Materiales incompatibles. El calor y el contacto con ácidos o lejía pueden liberar gases muy tóxicos.

10.5 Materiales incompatibles

Ácidos, agentes oxidantes.

10.6 Productos de descomposición peligrosos

Óxidos de carbono, óxidos de sodio.

Sección 11: Información toxicológica

11.1 Información sobre efectos toxicológicos

Componentes		
Tiocianato de guanidina (5 % A 10 %)	593-84-0	**Toxicidad aguda:** Intraperitoneal-Ratón LD50 • 300 mg/kg
Glicerol (1 % A 5 %)	56-81-5	**Toxicidad aguda:** Ingestión/Oral-Rata LD50 • 12600 mg/kg; *Conductual*: **Anestesia general**; *Conductual*: **Debilidad muscular**; *Hígado*: **Otros cambios**; **Irritación:** Ojo-conejo • 500 mg 24 horas • Irritación leve; Piel-conejo • 500 mg 24 horas • Irritación leve; **Toxicidad multidosis:** Ingestión/Oral-Ratón TDLo • 560 g/kg 8 semana(s)-Continuo; *Pulmones, tórax o respiración*: **Cambio estructural o funcional en tráquea o bronquios**; Ingestión/oral-Ratón TDLo• 2800 mg/kg 25 semanas-Continuo; *Piel y apéndices: Otros*: **Tumores**; *Oncógeno*: **Facilita la acción de carcinógenos conocidos**; **Mútageno:** Análisis citogenético • Ingestión/Oral-Rata • 1 g/kg; Inhibición ADN • Vía humana no informada • Linfocitos (célula somática) • 200 mmol/L; **Reproductivo:** Ingestión/Oral-Rata TDLo • 100 mg/kg (1D macho); *Efectos reproductivos: Efectos sobre fertilidad*: **Mortalidad post-implantación**; **Tumorigénesis/carcinógeno:** Ingestión/Oral-ratón TDLo • 87,5 g/kg 25 semanas-Intermitente; *Oncogénico*: **Agente oncógeno equívoco por criterios RTECS**; *Pulmones, tórax o respiración*: **Tumores**; *Oncógeno*: **Facilita la acción de carcinógenos conocidos**

Propiedades del SGA	Clasificación
Toxicidad aguda	**UE/CLP**•Faltan datos **SGA de la ONU**•Toxicidad aguda - Oral 5 - ATEmix (oral) = 5000 mg/kg **HCS 2012 de la OSHA**•Faltan datos
Corrosión/irritación cutánea	**UE/CLP**•Faltan datos **SGA de la ONU**•Irritación cutánea leve 3 **HCS 2012 de la OSHA**•Faltan datos
Daño/irritación ocular grave	**UE/CLP**•Faltan datos **SGA de la ONU**•Irritación ocular 2 **HCS 2012 de la OSHA**•Irritación ocular 2
Sensibilización cutánea	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Sensibilización respiratoria	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Riesgo de aspiración	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Carcinogenicidad	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos

Propiedades del SGA	Clasificación
Mutagenicidad de células germinales	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Toxicidad para la reproducción	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-SE	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-RE	**UE/CLP**•Faltan datos **SGA de la ONU**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos

Efectos potenciales en la salud

Inhalación
Agudo (inmediato) Puede causar irritación.
Crónico (demorado) No hay datos disponibles
Piel
Agudo (inmediato) Provoca irritación cutánea leve.
Crónico (demorado) No hay datos disponibles
Ojo
Agudo (inmediato) Provoca irritación ocular grave.
Crónico (demorado) No hay datos disponibles
Ingestión
Agudo (inmediato) Nocivo en caso de ingestión.
Crónico (demorado) No hay datos disponibles

Clave de abreviaturas
LD = Dosis letal
TD = Dosis tóxica

Sección 12: Información ecológica

12.1 Toxicidad

El tiocianato de guanidinio es nocivo para la vida acuática.

12.2 Persistencia y degradabilidad

Faltan datos de material.

12.3 Potencial bioacumulativo

Faltan datos de material.

12.4 Movilidad en suelo

Faltan datos de material.

12.5 Resultados de la evaluación de PBT y mPmB

No se ha realizado ninguna valoración de PBT y mPmB.

12.6 Otros efectos adversos

No se han encontrado estudios.

Sección 13: Consideraciones sobre la eliminación

13.1 Métodos de tratamiento de residuos

Residuos de productos Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

Residuos de embalaje Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

13.2 Información adicional

Los especímenes biológicos, incluidos cartuchos usados, deben tratarse como posibles transmisores de agentes infecciosos. Consulte con el personal de residuos medioambientales de su institución el procedimiento correcto de eliminación de cartuchos utilizados y de reactivos sin utilizar. Este material puede mostrar características de residuos peligrosos según la Ley de Recuperación y Conservación de Recursos (RCRA) de la EPA y necesitar requisitos específicos para su eliminación. Compruebe los reglamentos locales y estatales, ya que pueden ser diferentes a los reglamentos de eliminación federales. Las instituciones externas a EE. UU. deben comprobar los requisitos de eliminación de residuos peligrosos de su país.

Sección 14: Información de transporte

	14.1 Número ONU	14.2 Designación oficial de transporte de la ONU	14.3 Clases de riesgo de transporte	14.4 Grupo de embalaje	14.5 Riesgos para el medioambiente
DOT	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles
TDG	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles
IMO/IMDG	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles
IATA/ICAO	No hay datos disponibles	No regulado	No hay datos disponibles	No hay datos disponibles	No hay datos disponibles

14.6 Precauciones especiales para el usuario

Ninguno especificado.

14.7 Transporte a granel de acuerdo con el Anexo II del MARPOL 73/78 y el código IBC

Faltan datos.

Sección 15: Información reglamentaria

15.1 Legislación/reglamentos de seguridad, salud y medio ambiente específicos para la sustancia o mezcla

Clasificaciones de riesgo de la ley SARA Agudo, incendio

Inventario						
Componente	**CAS**	**DSL de Canadá**	**NDSL de Canadá**	**EINECS de la UE**	**ELNICS de la UE**	**TSCA**
Glicerol	56-81-5	Sí	No	Sí	No	Sí
Tiocianato de guanidina	593-84-0	Sí	No	Sí	No	Sí

Canadá

Mano de obra

Canadá - WHMIS - Clasificación de sustancias

•Glicerol	56-81-5	Producto incontrolado según los criterios de clasificación del WHMIS
•Tiocianato de guanidina	593-84-0	No listado

Canadá - WHMIS - Lista de divulgación de ingredientes

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

Medio ambiente

Canadá - CEPA - Lista de sustancias prioritarias

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

Estados Unidos

Mano de obra

EE. UU. - OSHA - Administración de seguridad de procesos - Productos químicos muy peligrosos

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - OSHA - Productos químicos regulados de manera específica

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

Medio ambiente

EE. UU. - CAA (Clean Air Act) - 1990 Contaminantes peligrosos del aire

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sustancias peligrosas y sus cantidades declarables

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - CERCLA/SARA - Radionucleidos y sus cantidades declarables

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades declarables de sustancias extremadamente peligrosas según la EPCRA

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades para la planificación de umbrales de sustancias extremadamente peligrosas

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 313 - Informes de emisión

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

EE. UU. - CERCLA/SARA - Sección 313 - Lista de productos químicos PBT

•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

Estados Unidos - California

Medio ambiente

EE. UU. - California - Proposición 65 - Lista de productos cancerígenos		
•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado
EE. UU. - California - Proposición 65 - Toxicidad en el desarrollo		
•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado
EE. UU. - California - Proposición 65 - Niveles máximos de dosis permitidos (MADL)		
•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado
EE. UU. - California - Proposición 65 - Sin niveles de riesgo significativos (NSRL)		
•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado
EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Mujeres		
•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado
EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Hombres		
•Glicerol	56-81-5	No listado
•Tiocianato de guanidina	593-84-0	No listado

15.2 Evaluación de seguridad del producto químico

No se ha llevado a cabo ninguna evaluación de seguridad química.

Sección 16: Información adicional

Frases pertinentes (código y texto completo)

H302 - Nocivo en caso de ingestión.
H412 - Nocivo para los organismos acuáticos, con efectos nocivos duraderos.
EUH031 - Libera gas tóxico al entrar en contacto con ácidos.

Declaración/descargo de responsabilidad

La información anterior está basada en los datos que tenemos y la consideramos correcta. Debido a que la información puede aplicarse bajo condiciones externas a nuestro control y con las que podemos no estar familiarizados, no asumimos ninguna responsabilidad por los resultados de su uso, y todas las personas que la reciban deberán determinar por sí mismas los efectos, propiedades, protecciones y eliminación correspondientes a sus condiciones particulares. No se efectúa ninguna representación ni garantía, expresa o implícita (incluida ninguna garantía de adecuación o comerciabilidad para un objetivo concreto) respecto a los materiales, la precisión de esta información, los resultados obtenidos de su uso ni los riesgos relacionados con dicho uso del material. Tenga precaución al manipular y utilizar el material. La información superior se considera precisa y se ofrece de buena fe. Proporcionamos toda la información relacionada con la manipulación prevista del material en la fecha de publicación. Sin embargo, en caso de ocurrir un incidente adverso asociado a este producto, esta ficha de datos de seguridad no es ni debe utilizarse como sustituto de la consulta con personal formado adecuadamente.

Ficha de Dados de Segurança *Xpert Trichomonas*
Data de entrada em vigor: Setembro de 2016
Data de substituição: Novembro de 2015

Secção 1: Identificação da substância/mistura e da empresa/projeto

1.1 Identificador do Produto

Nome do Produto **Xpert Trichomonas**
Código do produto 900-0657; GXTV-10; GXTV-CE-10

1.2 Usos relevantes da substância ou mistura identificados, e usos não recomendados

Uso(s) relevante(s) identificado(s) Utilização laboratorial

1.3 Detalhes do fornecedor da ficha de dados de segurança do material

Fabricante Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Estados Unidos da América
www.cepheid.com
EUA: techsupport@cepheid.com
Telefone (Geral) 1 (888) 838-3222 - Opção 2 (EUA)
Telefone (Geral) 1 (408) 541-4191 - Fora dos EUA

1.4 Número de telefone de emergência

Fabricante 1 (800) 424-9300 - CHEMTREC - Emergência durante 24 h
Fabricante 1 (703) 741-5500 - Fora dos EUA

Secção 2: Identificação dos riscos

UE/CEE

Segundo: Regulamentação (CE) N.º 1272/2008 (CLP)/REACH 1907/2006 [alterada pela 453/2010]

2.1 Classificação da substância ou mistura

CLP A seguinte ficha de dados de segurança destina-se apenas ao produto final acabado usado em laboratório. Contém componentes líquidos, alguns dos quais sob a forma de pós liofilizados e reagentes que se encontram no cartucho e numa garrafa Nalgene. Todos os reagentes são líquidos incolores e transparentes. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR.
Não classificado

2.2 Elementos do rótulo

CLP

Declarações de risco Não são necessários elementos do rótulo

2.3 Outros riscos

CLP Este material não é considerado perigoso conforme Regulamentação (CE) N.º 1272/2008 (CLP).

GHS da ONU

Segundo: Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS) da ONU

2.1 Classificação da substância ou mistura

GHS da ONU

Toxicidade oral aguda 5
Irritação cutânea ligeira 3
Irritação ocular 2

2.2 Elementos do rótulo

GHS da ONU

AVISO

Declarações de risco

Possibilidade de ser nocivo por ingestão
Provoca irritação cutânea ligeira
Provoca irritação ocular grave

Declarações de precaução

Prevenção

Lavar cuidadosamente após manuseamento.
Usar luvas de proteção/vestuário de proteção/proteção ocular/proteção facial.

Resposta

Caso sinta indisposição, contacte um CENTRO DE INFORMAÇÃO ANTIVENENOS ou um médico.
Em caso de irritação cutânea: consulte um médico.
SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar.
Caso a irritação ocular persista: consulte um médico.

2.3 Outros riscos

GHS da ONU

Este produto é considerado perigoso de acordo com o Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS).

Estados Unidos da América (EUA)
Segundo: OSHA 29 CFR 1910.1200 HCS

2.1 Classificação da substância ou mistura

OSHA HCS 2012

Irritação ocular 2

2.2 Elementos do rótulo

OSHA HCS 2012

AVISO

Declarações de risco

Provoca irritação ocular grave

Declarações de precaução

Prevenção

Lavar cuidadosamente após manuseamento.
Usar luvas de proteção/vestuário de proteção/proteção ocular/proteção facial.

Resposta SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar.
Caso a irritação ocular persista: consulte um médico.

2.3 Outros riscos

OSHA HCS 2012 Este produto é considerado perigoso ao abrigo da Regulamentação dos Estados Unidos da América (Norma sobre Comunicação de Perigos - 29 CFR 1910.1200).

Canadá
Segundo: WHMIS

2.1 Classificação da substância ou mistura

WHMIS Outros efeitos tóxicos - D2B

2.2 Elementos do rótulo

WHMIS

Outros efeitos tóxicos - D2B

2.3 Outros riscos

WHMIS No Canadá, o produto acima referido é considerado perigoso ao abrigo do Sistema de Informação de Materiais Perigosos no Local de Trabalho (WHMIS).

2.4 Outras informações

Esta Ficha de Dados de Segurança destina-se apenas ao produto final acabado conforme usado em laboratório ou contexto clínico. Este produto é um cartucho que contém reagentes líquidos e pós liofilizados. Os perigos indicados baseiam-se nos reagentes contidos no cartucho. Não se espera nenhuma exposição aos reagentes neste cartucho durante a utilização normal.

Secção 3: Composição/informações sobre os ingredientes

3.1 Substâncias

O material não cumpre os critérios de uma substância.

3.2 Misturas

Composição					
Nome do produto químico	**Identificadores**	**%**	**LD50/LC50**	**Classificações de acordo com regulamentos/diretivas**	**Comentários**
Tiocianato de guanidina	**CAS:** 593-84-0 **EINECS:** 209-812-1	5% A 10%	NDA	**GHS da ONU:** Tox. aguda 4 (Oral); Irrit. pele 3; Irrit. olhos 2B; Toxicidade aguda em ambiente aquático 3; Aquática Crónica 3 **UE CLP:** Tox. aguda 4, H302; EUH031; Aquática Crónica 3, H412 **OSHA HCS 2012:** Tox. aguda 4 (Orl); Irrit. olhos 2B	NDA
Glicerol	**CAS:** 56-81-5 **Número na CE:** 200-289-5	1% A 5%	Ingestão/Oral-Rato LD50 • 12 600 mg/kg	**GHS da ONU:** Irrit. ocular 2; Irrit. pele 3 **UE CLP:** Irrit. ocular 2, H319 **OSHA HCS 2012:** Irrit. ocular 2	NDA

Consultar o texto completo das declarações de perigo na Secção 16.

Secção 4: Medidas de primeiros socorros

4.1 Descrição das medidas de primeiros socorros

Inalação Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Mover a vítima para o ar livre. Administrar oxigénio se a respiração estiver difícil. Não usar o método boca-a-boca se a vítima tiver inalado a substância; ministre respiração artificial com o auxílio de uma máscara de bolso equipada com uma válvula de 1 via ou outro dispositivo médico de respiração adequado. Administrar respiração artificial se a vítima não estiver a respirar.

Pele Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Para um pequeno contacto com a pele, evitar espalhar o material pela pele não afetada. Em caso de contacto com a substância, lavar imediatamente a pele com água corrente por pelo menos 20 minutos. Despir e isolar a roupa contaminada.

Olhos Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de contacto com a substância, lavar imediatamente os olhos com água corrente por pelo menos 20 minutos. Caso a irritação ocular persista: consulte um médico.

Ingestão Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de ingestão, lavar a boca com água (apenas se a pessoa estiver consciente). NÃO provocar o vómito. Não usar o método boca-a-boca se a vítima tiver ingerido a substância. Em caso de ingestão, consultar um médico imediatamente.

4.2 Sintomas e efeitos mais importantes, tanto agudos quanto retardados

Consultar a Secção 11 - Informação Toxicológica.

4.3 Indicação de qualquer cuidado médico imediato e tratamento especial necessários

Notas para o Médico Todos os tratamentos devem basear-se nos sinais e sintomas de perturbações observados no paciente. Deve ser considerada a possibilidade de sobrexposição a outros materiais além deste produto.

Secção 5: Medidas de combate a incêndios

5.1 Meios de extinção

Meios de extinção adequados GRANDES INCÊNDIOS: Produto químico seco, CO2, espuma resistente ao álcool ou água pulverizada.
PEQUENOS INCÊNDIOS: Produto químico seco, CO2 ou água pulverizada.

Meios de extinção inadequados Sem dados disponíveis

5.2 Riscos especiais provocados pela substância ou mistura

Riscos de Incêndios e Explosões Incomuns	Pode emitir vapores tóxicos de óxidos de carbono, óxidos de enxofre e óxidos de azoto.
Produtos de combustão de risco	Sem dados disponíveis

5.3 Conselhos para bombeiros

Roupas protetoras estruturais de bombeiros fornecem APENAS proteção limitada em caso de incêndio; não são eficientes em situações de derramamentos, onde é possível o contacto direto com a substância.
Usar roupa protetora contra produtos químicos que seja especificamente recomendada pelo fabricante. Poderá fornecer proteção térmica mínima ou nenhuma proteção.
Usar aparelho de respiração autónomo de pressão positiva (SCBA).
PEQUENOS INCÊNDIOS: Se não houver perigos, mover os recipientes da área de incêndio.

Secção 6: Medidas contra Libertação Acidental

6.1 Precauções individuais, equipamento protetor e procedimentos em emergências

Precauções pessoais	No caso de um cartucho se partir, aplicam-se estas precauções de proteção individual. Usar vestuário de proteção adequado. Não andar sobre material derramado. Não tocar em recipientes danificados ou material derramado a não ser que esteja a usar vestuário de proteção adequado. Ventilar áreas fechadas.
Procedimentos de emergência	Não se prevê a necessidade de procedimentos de emergência se o material for usado em condições normais e de acordo com as recomendações.

6.2 Precauções ambientais

Evitar a entrada em cursos de água, esgotos, caves ou áreas confinadas.

6.3 Métodos e material para contenção e limpeza

Medidas de Contenção/ Limpeza	Em caso de derrames pequenos, usar luvas e absorver o derrame com papel absorvente. Não eliminar os materiais derramados através do sistema de esgotos.

6.4 Referências para outras secções

Consultar a Secção 8 - Controlo da Exposição/Proteção Individual e a Secção 13 - Considerações relativas à eliminação.

Secção 7: Manuseamento e armazenamento

7.1 Precauções para o manuseamento seguro

Manuseamento	Não necessita de manuseamento especial. Se o cartucho se partir, evitar o contacto com os reagentes derramados. Evitar o contacto com a pele e os olhos.

7.2 Condições para armazenamento seguro, incluindo quaisquer incompatibilidades

Armazenamento	Armazenar de acordo com a documentação do produto. Manter afastado de materiais incompatíveis. Armazenar em local fechado à chave. Guardar o recipiente/embalagem bem fechado em local fresco e bem ventilado.

7.3 Utilização(ões) Final(is) Específica(s)

Consultar a Secção 1.2 - Uso(s) final(is) específico(s)

Secção 8: Controlos e exposição/proteção individual

8.1 Parâmetros de controlo

Limites de Exposição/Orientações		
	Resultado	**OSHA**
Glicerol (56-81-5)	TWA	TWA de 15 mg/m3 (névoa, total em partículas); TWA de 5 mg/m3 (névoa, fração respirável)
Tiocianato de guanidina	TWA	TWA de 5 mg/m3 (sob a forma de CN) *sob a forma de compostos de cianeto*

8.2 Controlos de exposição

Medidas/Controlos de Engenharia Deve usar-se uma boa ventilação geral. Os níveis de ventilação devem estar adequados às condições. Se aplicável, usar confinamento de processos, ventilação por exaustão local ou outro controlo técnico para manter os níveis de partículas disseminadas por via aérea em suspensão abaixo dos limites de exposição recomendados. Caso não tenham sido definidos limites, manter os níveis destas partículas em suspensão num nível aceitável.

Equipamento de Proteção Individual

Respiratório Seguir as regulamentações da máscara OSHA que se encontram na norma 29 CFR 1910.134 ou na Norma Europeia EN 149. Em caso de ultrapassagem dos limites de exposição ou da ocorrência de sintomas, usar um aparelho de respiração aprovado pelo NIOSH/MSHA ou pela Norma Europeia EN 149.

Olhos/Face Usar óculos de proteção contra salpicos de produtos químicos.

Pele/Corpo Usar vestuário de proteção.

Controlos Ambientais de Exposição Seguir as melhores práticas para gestão do local e eliminação dos resíduos.

Chave para abreviaturas
OSHA = Agência para a Segurança e Saúde no Trabalho
TWA = A Média Ponderada por tempo tem por base a exposição 8 h/dia, 40 h/semana

Secção 9: Propriedades físicas e químicas

9.1 Informações sobre Propriedades Físicas e Químicas

Descrição do material			
Forma física	Líquido	Aspeto/Descrição	As esferas são componentes brancos sólidos em cartuchos; os reagentes são líquidos transparentes que foram inicialmente tamponados em soluções aquosas. Os componentes são inodoros.
Cor	Branco/transparente	Odor	Inodoro
Limiar do Odor	Dados em falta		
Propriedades gerais			
Ponto de ebulição	100 °C (212 °F)	Ponto de fusão/Ponto de congelamento	0 °C (32 °F)
Temperatura de decomposição	Dados em falta	pH	7 a 9 Reagente de lise #1 (GTC pH (3,7-4,1)). Reagente de lise #2 (hidróxido de sódio < 1% pH 14).
Gravidade específica/ Densidade relativa	Dados em falta	Solubilidade em água	Dados em falta
Viscosidade	Dados em falta	Propriedades explosivas	Dados em falta
Propriedades Oxidantes:	Dados em falta		
Volatilidade			
Pressão do vapor	Dados em falta	Densidade do vapor	Dados em falta
Taxa de evaporação	Dados em falta		
Inflamabilidade			
Ponto de inflamação	182,2222 °C a 293,3333 °C (360 °F a 560 °F) (Reagente de ligação)	UEL	Dados em falta
LEL	Dados em falta	Autoignição	Dados em falta
Inflamabilidade (sólido/gasoso)	Dados em falta		
Ambiental			
Coeficiente de partição octanol/água	Dados em falta		

9.2 Outras Informações

Não foram observados parâmetros físico-químicos adicionais.

Secção 10: Estabilidade e reatividade

10.1 Reatividade

Desconhecida reação perigosa em condições normais de utilização.

10.2 Estabilidade química

Estável

10.3 Possibilidade de reações perigosas

Não haverá polimerização perigosa.

10.4 Condições a evitar

Materiais incompatíveis. Calor, o contacto com ácidos ou lixívia pode causar a libertação de gás muito tóxico.

10.5 Materiais incompatíveis

Ácidos, agentes oxidantes.

10.6 Produtos de decomposição perigosos

Óxidos de carbono, óxidos de sódio.

Secção 11: Informações toxicológicas

11.1 Informações sobre efeitos toxicológicos

Componentes		
Tiocianato de guanidina (5% A 10%)	593-84-0	**Toxicidade aguda:** Intraperitoneal-Ratinho LD50 • 300 mg/kg
Glicerol (1% A 5%)	56-81-5	**Toxicidade aguda:** Ingestão/Oral-Rato LD50 • 12 600 mg/kg; *Comportamental*: **Anestésico geral**; *Comportamental*: **Fraqueza muscular**; *Fígado*: **Outras alterações**; **Irritação:** Olho-Coelho • 500 mg 24 horas • Irritação ligeira; Pele-Coelho • 500 mg 24 horas • Irritação ligeira; **Toxicidade multi-dose:** Ingestão/Oral-Ratinho TDLo • 560 g/kg 8 semanas-Contínua; *Pulmões, tórax ou respiração*: **Alteração estrutural ou funcional na traqueia ou nos brônquios**; Ingestão/Oral-Ratinho TDLo • 2800 mg/kg 25 semanas-Contínua; *Pele e apêndices: Outros*: **Tumores**; *Tumorigénico*: **Facilita a ação de um cancerígeno conhecido**; **Mutagénico:** Análise citogenética • Ingestão/Oral-Rato • 1 g/kg; Inibição do ADN • Via não comunicada-Humanos • Linfócito (célula somática) • 200 mmol/L; **Reprodução:** Ingestão/Oral-Rato TDLo • 100 mg/kg (1D macho); *Efeitos na reprodução: Efeitos na fertilidade*: **Mortalidade pós-implantação**; **Tumorigénico/Carcinogénico:** Ingestão/Oral-Rato TDLo • 87,5 g/kg 25 semanas-Intermitente; *Tumorigénico*: **Agente tumorigénico suspeitado pelos critérios RTECS**; *Pulmões, tórax ou respiração*: **Tumores**; *Tumorigénico*: **Facilita a ação de um cancerígeno conhecido**

Propriedades do GHS	Classificação
Toxicidade aguda	**UE/CLP**•Dados em falta **GHS ONU**•Toxicidade aguda - Oral 5 - ATEmix (oral) = 5000 mg/kg **OSHA HCS 2012**•Dados em falta
Corrosão/irritação cutânea	**UE/CLP**•Dados em falta **GHS da ONU**•Irritação cutânea ligeira 3 **OSHA HCS 2012**•Dados em falta
Lesão/irritação ocular grave	**UE/CLP**•Dados em falta **GHS da ONU**•Irritação ocular 2 **OSHA HCS 2012**•Irritação ocular 2
Sensibilização da pele	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta
Sensibilização respiratória	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta
Perigo de aspiração	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta
Carcinogenicidade	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta

Propriedades do GHS	Classificação
Mutagenicidade de células germinativas	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta
Toxicidade da reprodução	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-SE	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-RE	**UE/CLP**•Dados em falta **GHS da ONU**•Dados em falta **OSHA HCS 2012**•Dados em falta

Potenciais efeitos na saúde

Inalação
Agudos (imediatos) Pode provocar irritação.
Crónicos (retardados) Sem dados disponíveis

Pele
Agudos (imediatos) Provoca irritação cutânea ligeira.
Crónicos (retardados) Sem dados disponíveis

Olhos
Agudos (imediatos) Provoca irritação ocular grave.
Crónicos (retardados) Sem dados disponíveis

Ingestão
Agudos (imediatos) Pode ser nocivo por ingestão.
Crónicos (retardados) Sem dados disponíveis

Chave para abreviaturas
LD = Dose letal
TD = Dose tóxica

Secção 12: Informações ecológicas

12.1 Toxicidade

O tiocianato de guanidínio é nocivo para os organismos aquáticos.

12.2 Persistência e degradabilidade

Dados dos materiais em falta.

12.3 Potencial bioacumulativo

Dados dos materiais em falta.

12.4 Mobilidade no solo

Dados dos materiais em falta.

12.5 Resultados de avaliação PBT e vPvB

Não foi feita a avaliação PBT e vPvB.

12.6 Outros efeitos adversos

Não foram encontrados estudos.

Secção 13: Considerações sobre a eliminação

13.1 Métodos de tratamento de dejetos

Produto residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

Embalagem residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

13.2 Outras informações

As amostras biológicas, incluindo cartuchos usados, devem ser tratadas como potenciais fontes de transmissão de agentes infeciosos. Consultar os técnicos responsáveis pelos resíduos ambientais da sua instituição relativamente à eliminação correta de cartuchos usados e reagentes não utilizados. Este material pode apresentar características de resíduos perigosos segundo a Lei de Recuperação e Conservação de Recursos (RCRA) da Agência de Proteção Ambiental (EPA), que exijam requisitos de eliminação específicos. Verificar as regulamentações estaduais e locais, uma vez que poderão diferir das regulamentações federais de eliminação de resíduos. As instituições fora dos EUA devem verificar os requisitos relativos à eliminação de resíduos perigosos dos respetivos países.

Secção 14: Informações sobre transporte

	14.1 Número na ONU	14.2 Nome de transporte adequado (ONU)	14.3 Classe(s) de transporte de risco	14.4 Grupo de embalagem	14.5 Perigos ambientais
DOT	NDA	Não regulamentado	NDA	NDA	NDA
TDG	NDA	Não regulamentado	NDA	NDA	NDA
IMO/IMDG	NDA	Não regulamentado	NDA	NDA	NDA
IATA/ICAO	NDA	Não regulamentado	NDA	NDA	NDA

14.6 Precauções especiais para o utilizador

Nenhuma especificada.

14.7 Transporte por volume segundo o Anexo II de MARPOL 73/78 e do Código do IBC

Dados em falta.

Secção 15: Informações regulamentares

15.1 Regulamentos/legislação de segurança, saúde e ambientais, específicos da substância ou mistura

Classificações de Risco SARA Agudo, Incêndio

Inventário						
Componente	**CAS**	**DSL (Canadá)**	**NDSL (Canadá)**	**EINECS (UE)**	**ELNICS (UE)**	**TSCA**
Glicerol	56-81-5	Sim	Não	Sim	Não	Sim
Tiocianato de guanidina	593-84-0	Sim	Não	Sim	Não	Sim

Canadá

Trabalho

Canadá - WHMIS - Classificação de Substâncias

•Glicerol	56-81-5	Produto não controlado de acordo com os critérios de classificação do WHMIS
•Tiocianato de guanidina	593-84-0	Não listado

Canadá - WHMIS - Lista de Divulgação de Ingredientes

•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado

Ambiente

Canadá - CEPA - Lista de Substâncias Prioritárias

•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado

Estados Unidos da América

Trabalho

E.U.A. - OSHA - Gestão de Segurança do Processo - Produtos Químicos Altamente Perigosos

•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado

E.U.A. - OSHA - Químicos com Regulamentação Específica

•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado

Ambiente

E.U.A. - CAA (Lei do Ar Puro) - 1990 Poluentes Atmosféricos Perigosos		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - CERCLA/SARA - Substâncias Perigosas e Respetivas Quantidades de Comunicação Obrigatória		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - CERCLA/SARA - Radionuclídeos e Respetivas Quantidades de Comunicação Obrigatória		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - CERCLA/SARA - Secção 302 Quantidades de Comunicação Obrigatória de Substâncias Extremamente Perigosas da EPCRA		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - CERCLA/SARA - Secção 302 Planeamento de Quantidades Limite de Substâncias Extremamente Perigosas		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - CERCLA/SARA - Secção 313 - Relatório de Emissão		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - CERCLA/SARA - Secção 313 - Listagem de Produtos Químicos PBT		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado

Estados Unidos da América - Califórnia

Ambiente

E.U.A. - Califórnia - Proposta 65 - Lista de Substâncias Cancerígenas		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para o Desenvolvimento		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Níveis Máximos de Dose Permitidos (MADL)		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Sem Níveis de Risco Significativos (NSRL)		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Mulheres		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Homens		
•Glicerol	56-81-5	Não listado
•Tiocianato de guanidina	593-84-0	Não listado

15.2 Avaliação da Segurança Química

Não foi efetuada qualquer Avaliação da Segurança Química.

Secção 16: Outras informações

Frases relevantes (código e texto)

H302 - Nocivo por ingestão
H412 - Nocivo para os organismos aquáticos com efeitos duradouros
EUH031 - Em contacto com ácidos liberta gases tóxicos.

Renúncia/ Declaração de responsabilidade

A informação supramencionada baseia-se em dados que nos foram disponibilizados e é tida como correta. Dado que a informação pode ser aplicada em condições fora do nosso controlo e com as quais podemos não estar familiarizados, não assumimos qualquer responsabilidade pelo resultado da sua utilização, e todas as pessoas que a recebam têm de determinar individualmente os efeitos, as propriedades, as proteções e os procedimentos de eliminação que se aplicam às suas condições particulares. Não se assume qualquer representação ou garantia, implícita ou explicitamente (incluindo garantia de adequação ou comerciabilidade para uma finalidade específica) em relação aos materiais, à exatidão desta informação, aos resultados obtidos decorrentes da sua utilização ou a perigos relacionados com a utilização deste material. Deve-se ter cuidado no manuseamento e utilização deste material. A informação anterior é disponibilizada de boa-fé e é tida como exata. À data de emissão, fornecemos toda a informação relevante para um manuseamento previsível do material. No entanto, caso ocorra um incidente adverso associado a este produto, esta Ficha de Dados de Segurança não substitui, nem se pretende que substitua, a consulta de um profissional com formação adequada.

Chave para abreviaturas
NDA = Nenhuns Dados Disponíveis

Паспорт безопасности материала *Xpert Trichomonas*
Дата вступления в силу: сентябрь, 2016 г.
Отменяет версию документа за: ноябрь, 2015 г.

Раздел 1: Общие сведения о веществе/смеси и производителе

1.1 Идентификатор продукта

Наименование продукта **Xpert Trichomonas**
Код продукта 900-0657; GXTV-10; GXTV-CE-10

1.2 Рекомендованные и не рекомендованные способы применения вещества или смеси

Рекомендованные способы применения Для использования в лабораторных условиях

1.3 Сведения об организации, предоставившей паспорт безопасности материала

Производитель Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States (США)
www.cepheid.com
США: techsupport@cepheid.com
Телефон (общий) 1 (888) 838-3222 - США, дополнит. 2
Телефон (общий) 1 (408) 541-4191 - За пределами США

1.4 Телефон для экстренной связи

Производитель 1 (800) 424-9300 - CHEMTREC - круглосуточный телефон экстренного вызова
Производитель 1 (703) 741-5500 - За пределами США

Раздел 2: Идентификация опасности

ЕС/ЕЭС

Согласно: Регламенту ЕК (ЕС) № 1272/2008 (CLP)/REACH 1907/2006 [с поправками, внесенными постановлением 453/2010]

2.1 Классификация вещества или смеси

Регламент CLP Следующий паспорт безопасности материала действителен только для готового продукта, используемого в лабораторных условиях. Содержит жидкие компоненты, некоторые из которых лиофилизированы, а также реактивы, содержащиеся в картридже и во флаконе Nalgene. Все реактивы представляют собой прозрачные бесцветные жидкости. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1)&(2).
Не классифицируется

2.2 Элементы маркировки

Регламент CLP

Указания на опасность Маркировка не требуется.

2.3 Другие факторы опасности

Регламент CLP Согласно Регламенту ЕК № 1272/2008 (CLP) этот материал не считается опасным.

СГС ООН
Согласно: Согласованная на глобальном уровне система классификации опасности и маркировки химической продукции (СГС) ООН

2.1 Классификация вещества или смеси
СГС ООН

Острая токсичность, перорально, 5
Слабое раздражение кожи, 3
Раздражение глаз, 2

2.2 Элементы маркировки
СГС ООН

ВНИМАНИЕ!

Указания на опасность

Может быть вредно при проглатывании
Вызывает слабое раздражение кожи
Вызывает серьезное раздражение глаз

Меры предосторожности

Профилактика

После использования тщательно вымыть.
Пользуйтесь защитными перчатками, защитной одеждой, средствами защиты глаз/лица.

Реагирование

При плохом самочувствии обратиться в ТОКСИКОЛОГИЧЕСКИЙ ЦЕНТР или к врачу-специалисту/терапевту.
При раздражении кожи: обратиться за медицинской консультацией/помощью.
ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание.
Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

2.3 Другие факторы опасности
СГС ООН

В соответствии с Согласованной на глобальном уровне системой классификации опасности и маркировки химической продукции (СГС) данный продукт считается опасным.

США
Согласно: OSHA 29 CFR 1910.1200 HCS

2.1 Классификация вещества или смеси
OSHA HCS 2012

Раздражение глаз, 2

2.2 Элементы маркировки

OSHA HCS 2012

ВНИМАНИЕ!

Указания на опасность	Вызывает серьезное раздражение глаз
Меры предосторожности	
Профилактика	После использования тщательно вымыть. Пользуйтесь защитными перчатками, защитной одеждой, средствами защиты глаз/лица.
Реагирование	ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

2.3 Другие факторы опасности

OSHA HCS 2012 Согласно государственным нормам США (документ 29 CFR 1910.1200 - Стандарт-требование об оповещении об опасности) этот продукт считается опасным.

Канада
Согласно: WHMIS

2.1 Классификация вещества или смеси

WHMIS Другие токсические эффекты, D2B

2.2 Элементы маркировки

WHMIS

Другие токсические эффекты, D2B

2.3 Другие факторы опасности

WHMIS В Канаде указанное выше вещество согласно требованиям Информационной системы по опасным материалам на рабочих местах (WHMIS) считается опасным.

2.4 Дополнительная информация

Данный паспорт безопасности материала действителен только для готового продукта, используемого в лабораторных условиях. Продукт представляет собой картридж с жидкими и лиофилизированными реактивами. Источники опасности связаны с реактивами, содержащимися в картридже. В условиях нормальной эксплуатации контакт с реактивом в картридже исключен.

Раздел 3: Состав/информация о компонентах

3.1 Вещества

Материал не отвечает критериям классификации, применяемым к веществам.

3.2 Смеси

Состав					
Химическое наименование	**Идентификаторы**	**%**	**LD50/LC50**	**Классификация в соответствии с нормами/постановлениями**	**Комментарии**
Гуанидина тиоцианат	**CAS:** 593-84-0 **EINECS:** 209-812-1	ОТ 5% ДО 10%	Нет данных	**СГС ООН:** острая токсичность 4 (перорально); раздражение кожи 3; раздражение глаз 2B; острая токсичность для водной среды 3; токсично для водной среды при хроническом воздействии 3 **EU CLP:** острая токсичность 4, H302; EUH031; токсично для водной среды при хроническом воздействии 3, H412 **OSHA HCS 2012:** острая токсичность 4 (перорально); раздражение глаз 2B	Нет данных
Глицерин	**CAS:** 56-81-5 **Номер EC:** 200-289-5	ОТ 1% ДО 5%	Прием внутрь/ перорально-крыса LD50 • 12600 мг/кг	**СГС ООН:** раздражение глаз 2; раздражение кожи 3 **EU CLP:** раздражение глаз 2, H319 **OSHA HCS 2012:** раздражение глаз 2	Нет данных

См. раздел 16 с полным текстом указаний на опасность.

Раздел 4: Первая медицинская помощь

4.1 Описание мер первой медицинской помощи

Вдыхание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. Вынести пострадавшего на свежий воздух. При затрудненном дыхании дать кислород. При вдыхании вещества не применять искусственное дыхание рот-в-рот. Выполнить искусственное дыхание с помощью карманной маски с клапаном одностороннего действия или другого подходящего медицинского устройства. При остановке дыхания обеспечить искусственное дыхание/ИВЛ.

Кожа Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При незначительном контакте с кожей избегайте распространения материала на незатронутые участки. В случае контакта вещества с кожей незамедлительно промыть пораженный участок проточной водой в течение не менее чем 20 минут. Снять и изолировать загрязненную одежду.

Глаза Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. В случае попадания вещества незамедлительно промыть глаза проточной водой в течение не менее чем 20 минут. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

Проглатывание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При проглатывании прополоскать рот водой (только если человек находится в сознании). НЕ вызывать рвоту. Не применять искусственное дыхание рот-в-рот при проглатывании вещества. При проглатывании материала сразу же обратиться к врачу.

4.2 Наиболее важные симптомы и последствия, проявляющиеся немедленно и с задержкой

См. раздел 11, «Токсикологическая информация».

4.3 Признаки необходимости неотложной медицинской помощи и специального лечения

Примечания для врача Лечение основывать на наблюдаемых симптомах. Учитывать возможность одновременного чрезмерного воздействия на пациента и других веществ, помимо данного продукта.

Раздел 5: Меры противопожарной безопасности

5.1 Средства пожаротушения

Подходящие средства пожаротушения КРУПНЫЕ ПОЖАРЫ. Сухое химическое огнетушащее средство, углекислый газ (CO2), спиртоустойчивые пенообразователи, распыленная вода.
НЕБОЛЬШИЕ ПОЖАРЫ. Сухое химическое огнетушащее средство, углекислый газ (CO2), распыленная вода.

Непригодные средства пожаротушения Данные отсутствуют

5.2 Особые аспекты опасности вещества или смеси

Особая огне- и взрывоопасность Возможно выделение токсичных испарений: оксиды углерода, оксиды серы, оксиды азота.

Опасные продукты горения Данные отсутствуют

5.3 Рекомендации по пожаротушению

Защитная одежда пожарных для тушения пожаров в зданиях обеспечивает ограниченную защиту ТОЛЬКО в условиях пожара; она не является эффективным средством защиты при разливах с возможным непосредственным контактом с веществами.
Носить одежду для химической защиты, рекомендованную производителем. Она может быть малоэффективна или неэффективна в качестве тепловой защиты.
Использовать автономные дыхательные аппараты, работающие в режиме положительного давления.
НЕБОЛЬШИЕ ПОЖАРЫ. Уберите контейнеры из зоны пожара, если можете сделать это без риска.

Раздел 6: Меры по предотвращению и ликвидации последствий случайного выброса материала

6.1 Меры по обеспечению личной безопасности, средства защиты и действия в чрезвычайной ситуации

Меры по обеспечению личной безопасности В случае разбития картриджа актуальны указанные меры по обеспечению личной безопасности. Используйте соответствующую защитную одежду. Не ходите по разлитому/просыпанному материалу. Не прикасайтесь к поврежденным контейнерам или разлитому/просыпанному материалу, если нет соответствующей защитной одежды. Проветрите закрытые помещения.

Действия в чрезвычайных ситуациях Ожидается, что экстренные меры не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций.

6.2 Меры по защите окружающей среды

Не допускать попадания в водотоки, канализацию, подвалы и замкнутые пространства.

6.3 Методы и средства локализации и очистки

Методы и средства локализации и очистки При небольших разливах используйте перчатки. Для сбора вещества используйте бумажные полотенца. Не сливать пролитые вещества в канализацию.

6.4 Ссылки на другие разделы

См. раздел 8, «Меры контроля воздействия и средства индивидуальной защиты», и раздел 13, «Условия удаления в отходы».

Раздел 7: Правила обращения и хранения

7.1 Меры предосторожности при обращении с продуктом

Обращение Особое обращение не требуется. В случае разбития картриджа избегайте контакта с разлившимися реактивами. Избегать контакта с кожей и глазами.

7.2 Условия безопасного хранения и учет факторов несовместимости

Место хранения Хранить согласно указаниям на упаковке. Хранить вдали от несовместимых материалов. Хранить под замком. Хранить в плотно закрытом контейнере/упаковке в прохладном, хорошо проветриваемом месте.

7.3 Особые способы применения

См. раздел 1.2, «Рекомендованные способы применения».

Раздел 8: Меры контроля воздействия и средства индивидуальной защиты

8.1 Контрольные параметры

Предельно допустимые концентрации/рекомендации		
	Результат	**OSHA**
Глицерин (56-81-5)	TWA	15 мг/м3 TWA (туман, общая фракция частиц); 5 мг/м3 TWA (туман, фракция, проникающая в дыхательные пути)
Гуанидина тиоцианат	TWA	5 мг/м3 TWA (как CN) *как цианистые соединения*

8.2 Меры контроля воздействия

Инженерно-технические мероприятия/средства контроля Следует обеспечить хорошую общую вентиляцию. Интенсивность вентиляции должна соответствовать условиям хранения/использования. Если возможно, используйте изолированное рабочее пространство, местную вытяжную вентиляцию и прочие инженерно-технические средства для сдерживания концентрации вещества в воздухе на уровне ниже ПДК. Если ПДК не установлены, поддерживайте приемлемые концентрации вещества в воздухе.

Индивидуальные средства защиты

Защита органов дыхания	Соблюдайте рекомендации по использованию респираторов Управления охраны труда (OSHA) США, изложенные в документе 29 CFR 1910.134, или Европейского стандарта EN 149. При превышении ПДК или обнаружении признаков поражения используйте респираторы, одобренные Национальным институтом по безопасности и гигиене труда (NIOSH) США, Управлением по безопасности и охране труда в добывающей промышленности (MSHA) США или Европейским стандартом EN 149.
Защита глаз/лица	Носите очки химической защиты.
Защита кожных покровов/тела	Используйте защитную одежду.
Защита окружающей среды	Соблюдайте общие правила работы на объекте и удаления отходов.

Сокращения
OSHA = Управление охраны труда, США (Occupational Safety and Health Administration).
TWA = Средневзвешенная во времени концентрация, вычисляемая на основании воздействия в течение 8 часов в день, 40 часов в неделю.

Раздел 9: Физические и химические свойства

9.1 Информация о физических и химических свойствах

Описание материала			
Физическая форма	Жидкость	Внешний вид/описание	Гранулы представляют собой твердые белые компоненты, находящиеся в картриджах; реактивы — прозрачные жидкости, в основном буферизованные в водных растворах. Компоненты не имеют запаха.
Цвет	Белый/прозрачный	Запах	Без запаха
Порог ощущения запаха	Данные отсутствуют		
Общие свойства			
Точка кипения	100 °C (212 °F)	Температура плавления/замерзания	0 °C (32 °F)
Температура разложения	Данные отсутствуют	pH	от 7 до 9 Реактив для лизирования 1 (GTC pH (3,7-4,1)) Реактив для лизирования 2 (гидроксид натрия <1% pH 14).
Удельный вес/относительная плотность	Данные отсутствуют	Растворимость в воде	Данные отсутствуют
Вязкость	Данные отсутствуют	Взрывчатые свойства	Данные отсутствуют
Окислительные свойства:	Данные отсутствуют		
Летучесть			
Давление паров	Данные отсутствуют	Плотность паров	Данные отсутствуют
Интенсивность испарения	Данные отсутствуют		
Воспламеняемость			
Температура вспышки	от 182,2222 °C до 293,3333 °C (от 360 °F до 560 °F) (Реактив связывания)	ВКПВ (верхний предел взрываемости)	Данные отсутствуют
НПВ (нижний предел взрываемости)	Данные отсутствуют	Самовоспламенение	Данные отсутствуют
Воспламеняемость (в твердом, газообразном состоянии)	Данные отсутствуют		

В отношении окружающей среды			
Коэффициент распределения октанол/вода	Данные отсутствуют		

9.2 Дополнительная информация

Дополнительные физические и химические свойства не обнаружены.

Раздел 10: Стабильность и реакционная способность

10.1 Реакционная способность

В нормальных условиях использования опасные реакции неизвестны.

10.2 Химическая стабильность

Стабильно

10.3 Вероятность опасных реакций

Опасная полимеризация не происходит.

10.4 Условия, которых следует избегать

Несовместимые материалы. При нагревании и контакте с кислотами или раствором гипохлорита натрия возможно выделение очень токсичного газа.

10.5 Несовместимые материалы

Кислоты, окислители.

10.6 Опасные продукты разложения

Оксиды углерода, оксиды натрия.

Раздел 11: Токсикологическая информация

11.1 Информация о токсикологических последствиях

Компоненты		
Гуанидина тиоцианат (от 5% до 10%)	593-84-0	**Острая токсичность:** внутрибрюшинный-мышь LD50 • 300 мг/кг
Глицерин (ОТ 1% ДО 5%)	56-81-5	**Острая токсичность:** прием внутрь/перорально-крыса LD50 • 12600 мг/кг; *поведение*: **общее анестезирующее действие**; *поведение*: **мышечная слабость**; *печень*: **другие изменения**; **Раздражение:** глаза-кролик • 500 мг 24 часа • слабое раздражение; кожа-кролик • 500 мг 24 часа • слабое раздражение; **Токсичность при неоднократном введении:** прием внутрь/перорально-мышь TDLo • 560 г/кг 8 недель-непрерывный; *легкие, грудная клетка или дыхание*: **структурные или функциональные изменения в трахее или бронхах**; прием внутрь/перорально-мышь TDLo • 2800 мг/кг 25 недель-непрерывный; *кожа и придатки кожи: прочее*: **опухоли**; *способность приводить к развитию опухоли*: **усиливает действие известного канцерогена**; **Мутаген:** цитогенетический анализ • прием внутрь/перорально-крыса • 1 г/кг; подавление ДНК • неуказанный путь введения-человек • лимфоциты (соматические клетки) • 200 ммоль/л; **Влияние на репродуктивную функцию:** прием внутрь/перорально-крыса TDLo • 100 мг/кг (1 д. самцы); *влияние на репродуктивную функцию: влияние на фертильность*: **постимплантационная смертность**; **Развитие опухоли / канцероген:** прием внутрь/перорально-мышь TDLo • 87,5 г/кг 25 недель-прерывистый; *способность приводить к развитию опухоли*: **сомнительная способность вызывать развитие опухоли по критериям реестра RTECS**; *легкие, грудная клетка или дыхание*: **опухоли**; *способность приводить к развитию опухоли*: **усиливает действие известного канцерогена**

Свойства (СГС)	Классификация
Острая токсичность	**EU/CLP**•Данные отсутствуют **СГС ООН**•Острая токсичность - перорально - категория 5 - расчетная оценка острой токсичности ATEmix (пероральное введение) = 5000 мг/кг **OSHA HCS 2012**•Данные отсутствуют
Разъедающее/раздражающее воздействие на кожу	**EU/CLP**•Данные отсутствуют **СГС ООН**•Слабое раздражение кожи, категория 3 **OSHA HCS 2012**•Данные отсутствуют
Серьезное повреждение/раздражение глаз	**EU/CLP**•Данные отсутствуют **СГС ООН**•Раздражение глаз, категория 2 **OSHA HCS 2012**•Раздражение глаз, категория 2
Сенсибилизация кожи	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Сенсибилизация органов дыхания	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Опасность при аспирации	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Канцерогенность	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют

Свойства (СГС)	Классификация
Мутагенность для зародышевых клеток	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Токсическое действие на репродуктивную функцию	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Органоспецифическая токсичность при однократном воздействии (STOT-SE)	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют
Органоспецифическая токсичность при многократном воздействии (STOT-RE)	**EU/CLP**•Данные отсутствуют **СГС ООН**•Данные отсутствуют **OSHA HCS 2012**•Данные отсутствуют

Возможные последствия для здоровья

Вдыхание
Острые последствия Может вызывать раздражение.
Хронические последствия Данные отсутствуют
Кожа
Острые последствия Вызывает слабое раздражение кожи.
Хронические последствия Данные отсутствуют
Глаза
Острые последствия Вызывает серьезное раздражение глаз.
Хронические последствия Данные отсутствуют
Проглатывание
Острые последствия Может быть вредно при проглатывании.
Хронические последствия Данные отсутствуют

Сокращения
LD = Летальная доза
TD = Токсическая доза

Раздел 12: Информация о воздействии на окружающую среду

12.1 Токсичность

Гуанидина тиоцианат вреден для водных организмов.

12.2 Устойчивость и способность к разложению

Данные о материале отсутствуют.

12.3 Способность к биоаккумуляции

Данные о материале отсутствуют.

12.4 Подвижность в почве

Данные о материале отсутствуют.

12.5 Результаты оценки соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества»

Оценка соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества» не производилась.

12.6 Другие неблагоприятные последствия

Исследования не проводились.

Раздел 13: Условия удаления в отходы

13.1 Методы переработки отходов

Отходы продукта Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

Отходы упаковки Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

13.2 Дополнительная информация

К биологическим образцам, включая использованные картриджи, следует относиться как материалам, способным служить источником инфекционного заражения. По вопросам надлежащего удаления в отходы использованных картриджей и неиспользованных реактивов проконсультируйтесь с лицами, ответственными за обращение с отходами в вашей организации. Данный материал может иметь характеристики опасных отходов с особыми требованиями к удалению отходов, предусмотренные агентством EPA согласно Федеральному закону об охране и восстановлении ресурсов (RCRA) США. Ознакомьтесь с местными нормами, так как они могут отличаться от федеральных норм. Организации за пределами США должны ознакомиться с нормами обращения с опасными отходами, принятыми в соответствующих странах.

Раздел 14: Информация о транспортировке

	14.1 Номер ООН	14.2 Отгрузочное наименование ООН	14.3 Класс(-ы) опасности при транспортировке	14.4 Группа упаковки	14.5 Опасность для окружающей среды
DOT	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных
TDG	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных
IMO/IMDG	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных
IATA/ICAO	Нет данных	Не регулируется	Нет данных	Нет данных	Нет данных

14.6 Специальные меры предосторожности для пользователей

Не указаны.

14.7 Бестарная транспортировка в соответствии с Приложением II MARPOL 73/78 и Кодексом IBC

Данные отсутствуют.

Раздел 15: Нормативная информация

15.1 Правовые акты в сфере безопасности, защиты здоровья и окружающей среды/особые правовые акты, применимые к веществу или смеси

Класс опасности (SARA) Острая, пожароопасно

Реестр						
Компонент	**CAS**	**Канада, DSL**	**Канада, NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Глицерин	56-81-5	Да	Нет	Да	Нет	Да
Гуанидина тиоцианат	593-84-0	Да	Нет	Да	Нет	Да

Канада

Охрана труда

Канада - Информационная система по опасным материалам на рабочих местах (WHMIS) - Классификация веществ

•Глицерин	56-81-5	Продукт не подлежит контролю согласно критериям классификации WHMIS
•Гуанидина тиоцианат	593-84-0	Не числится

Канада - WHMIS - Перечень ингредиентов, информация о которых подлежит раскрытию

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

Окружающая среда

Канада - Закон Канады об охране окружающей среды (CEPA) - Список приоритетных веществ

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

Паспорт безопасности материала

Дата вступления в силу: сентябрь, 2016 г.
Отменяет версию документа за: ноябрь, 2015 г.

United States (США)

Охрана труда

США - Управление охраны труда (OSHA) - Обеспечение безопасности производственного процесса - Высокоопасные химические вещества

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - OSHA - Особо контролируемые химические вещества

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

Окружающая среда

США - Закон о чистом воздухе (CAA), 1990 - Опасные загрязняющие воздух вещества

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон об улучшении финансирования и перераспределении полномочий (SARA) - Опасные вещества и их подотчетные количества

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - CERCLA/SARA - Радионуклиды и их подотчетные количества

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - CERCLA/SARA - Раздел 302. Чрезвычайно опасные вещества. Закон о планировании действий при чрезвычайных ситуациях и праве общества на информацию (EPCRA) - подотчетные количества

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - CERCLA/SARA - Раздел 302. Чрезвычайно опасные вещества. Пороговые запланированные количества (TPQ)

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - CERCLA/SARA - Раздел 313. Оповещение о выбросах

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - CERCLA/SARA - Раздел 313. Список устойчивых биоаккумулятивных токсических веществ

•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

США - Калифорния

Окружающая среда

США - Калифорния - Предложение 65 - Список канцерогенов		
•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится
США - Калифорния - Предложение 65 - Эмбрифетотоксичность		
•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится
США - Калифорния - Предложение 65 - Предельно допустимые дозы (MADL)		
•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится
США - Калифорния - Предложение 65 - Концентрации веществ, не несущие значимого риска (NSRL)		
•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится
США - Калифорния - Предложение 65 - Влияние на женский организм		
•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится
США - Калифорния - Предложение 65 - Влияние на мужской организм		
•Глицерин	56-81-5	Не числится
•Гуанидина тиоцианат	593-84-0	Не числится

15.2 Оценка химической безопасности

Оценка химической безопасности не проводилась.

Раздел 16: Дополнительная информация

Соответствующие фразы (код и текст)

H302 - Вредно при проглатывании
H412 - Вредно для водных организмов с долгосрочными последствиями
EUH031 - При контакте с кислотами выделяет токсичный газ.

Отказ от ответственности/ ограничение ответственности

Представленные выше сведения основаны на доступных нам данных и считаются верными. В связи с тем, что представленная информация может быть использована в независящих от нас и неизвестных нам условиях, мы не несем ответственность за последствия ее использования, а все лица, получающие эту информацию, должны самостоятельно принимать решения относительно последствий применения, свойств, средств защиты и способов удаления в отходы в соответствии с конкретными условиями применения. Мы не заявляем, не даем каких-либо гарантий и поручительств, явных или подразумеваемых (включая гарантии пригодности или товарной пригодности для конкретной цели), в отношении материалов и точности информации, полученных при их использовании результатов, а также опасностей, связанных с использованием данного материала. При обращении с материалом и его использовании следует проявлять осторожность. Представленная выше информация передана добросовестно с уверенностью в ее точности. Мы предоставляем всю информацию, касающуюся предполагаемого использования материала, по состоянию на момент публикации. Однако в случае нежелательных последствий, связанных с данным продуктом, настоящий паспорт безопасности материала не является и не может являться заменой консультации с обученным специалистом.

安全数据表

生效日期：2016 年 9 月
更换日期：2015 年 11 月

Xpert Trichomonas

第 1 章：物质/混合物标识和公司/企业标识

1.1 产品识别

产品名称 Xpert Trichomonas
产品代码 900-0657; GXTV-10; GXTV-CE-10

1.2 物质或混合物的有关确定用途及不建议用途

有关确定用途 实验室使用

1.3 供应商安全数据表详情

制造商 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US：techsupport@cepheid.com
电话（通用） 1 (888) 838-3222 - 美国（选 2）
电话（通用） 1 (408) 541-4191 - 美国境外

1.4 紧急电话号码

制造商 1 (800) 424-9300 - CHEMTREC - 24 小时紧急电话
制造商 1 (703) 741-5500 - 美国境外

第 2 章：危险标识

EU/EEC
根据：第 1272/2008 号规章（欧共体）(CLP)/REACH 1907/2006 [修订版 453/2010]

2.1 物质或混合物的分类

CLP 以下 SDS 仅适用于用于实验室的最终成品。它含有液体组分，其中一些呈冷冻干燥粉末状和制剂状，装于盒子和 Nalgene 瓶子中。所有制剂均为清澈、无色液体。例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
未分类

2.2 标签元素

CLP

危险声明 不要求标签元素

2.3 其他危险

CLP 根据 (EC) 1272/2008 号条例 (CLP)，认为这种材料不是危险材料。

UN GHS
根据：联合国 (UN) 全球化学品统一分类和标签制度 (GHS)

2.1 物质或混合物的分类

UN GHS

急性经口毒性 5
轻度皮肤刺激 3
眼刺激 2

2.2 标签元素

UN GHS

警告

危险声明 如果吞入可能有害
导致轻度皮肤刺激
导致严重的眼睛刺激

防范声明

预防 处理之后要彻底清洗。
戴上防护手套/防护服/护目装备/护面装备。

响应 感到身体不适时，呼叫解毒中心或医生/医师。
如果发生皮肤刺激：获得医疗指导/就医治疗。
如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
如果眼睛刺激持续：获得医疗指导/就医治疗。

2.3 其他危险

UN GHS

根据全球统一分类和标签制度（GHS），认为该产品是危险品。

美国（US）
根据：OSHA 29 CFR 1910.1200 HCS

2.1 物质或混合物的分类

OSHA 的 HCS 2012

眼刺激 2

2.2 标签元素

OSHA 的 HCS 2012

警告

危险声明 导致严重的眼睛刺激

防范声明

预防 处理之后要彻底清洗。
戴上防护手套/防护服/护目装备/护面装备。

响应 如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
如果眼睛刺激持续：获得医疗指导/就医治疗。

2.3 其他危险

OSHA 的 HCS 2012 根据美国法规（29 CFR 1910.1200 - 危害通识标准），认为该产品是危险品。

加拿大
根据：WHMIS

2.1 物质或混合物的分类

WHMIS 其他毒性作用 - D2B

2.2 标签元素

WHMIS

其他毒性作用 - D2B

2.3 其他危险

WHMIS 在加拿大，根据工作场所有害材料信息系统（WHMIS），认为上述产品是危险品。

2.4 其他信息

以下 SDS 仅适用于用于实验室或临床环境中的最终成品。本产品是一个含液体制剂和冷冻干燥粉末的盒子，表述的风险是基于盒子中内含的制剂。在正常使用期间，应不会接触到合作内的制剂。

第 3 章：成分构成/信息

3.1 物质

该材料不符合某种物质的标准。

3.2 混合物

构成					
化学名称	**标识符**	**%**	**LD50/LC50**	**按规章/指令分类**	**注解**
异硫氰酸胍	**CAS：** 593-84-0 **EINECS：** 209-812-1	5%至10%	NDA	**UN GHS：** 急性毒性 4（经口）；皮肤刺激3；眼刺激 2B；水生急性 3；水生慢性 3 **EU CLP：** 急性毒性 4，H302； EUH031；水生慢性 3，H412 **OSHA HCS 2012：** 急性毒性 4（经口）；眼刺激 2B	NDA
甘油	**CAS：** 56-81-5 **EC 编号：** 200-289-5	1%至5%	摄入/口服-大鼠 LD50 • 12600 mg/kg	**UN GHS：** 眼刺激 2；皮肤刺激 3 **EU CLP：** 眼刺激 2，H319 **OSHA HCS 2012：** 眼刺激 2	NDA

完整的危险声明全文，请参阅第 16 章。

第 4 章：急救措施

4.1 急救措施描述

吸入 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。将受害者移至新鲜空气处。如果呼吸困难，就施用氧气。如果受害者吸入该物质，就不要使用口对口方法；借助配备单向阀或其他适当的呼吸医疗设备的袖珍面罩来给予人工呼吸。如果受害者没有呼吸，就给予人工呼吸。

皮肤 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。对于轻微的皮肤接触，避免使物质扩散到未受影响的皮肤上。在与物质接触的情况下，立即用流动的水冲洗眼睛至少20分钟。脱掉并隔离受污染的衣物。

眼睛 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。在与物质接触的情况下，立即用大量的水冲洗眼睛至少20分钟。如果眼睛刺激持续：获得医疗指导/就医治疗。

摄入 如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。如果吞入，用水漱口（只有当伤员意识清楚时）。切勿催吐。如果受害者摄入该物质，请勿使用口对口人工呼吸法。如果摄入，立即就医。

4.2 急性及缓发的最重要症状及效应

请参阅第 11 章 - 毒物学信息。

4.3 任何需要立即就医及特别治疗的症候

对医生的注释 所有治疗措施均应根据所观察到的患者的痛苦症状和体征进行。应考虑可能发生过度暴露于非本品材料的可能性。

第 5 章：消防措施

5.1 灭火介质

适用的灭火介质 大火：化学干粉、二氧化碳、抗溶性泡沫或喷水。
小火：化学干粉，二氧化碳或喷水。

不适用的灭火介质 无可用数据

5.2 由物质或混合物产生的特殊危险

异常火灾和爆炸危险 可能会散发碳氧化物、硫氧化物、氮氧化物有毒蒸气。

有害燃烧产物 无可用数据

5.3 供消防队员采纳的建议

建筑消防员的防护服在火情中只能提供有限的保护；它在可能与物质直接接触的溢出情况下无效穿上制造商专门推荐的化学防护服。
穿上制造商专门推荐的化学防护服。它可能提供很少或根本没有提供热保护。
配戴正压自给式呼吸装置 (SCBA)。
小火：如果能够无风险地完成，就从火区移出容器。

第 6 章：意外释放措施

6.1 个人预防措施、防护装备和紧急程序

个人预防措施 万一盒子断裂，则适用于这些个人预防措施。穿戴适当的防护服。切勿踩踏泄漏物。除非穿着适当的防护服，否则不要触碰损坏的容器或溢出的物质。使封闭的地区通风。

应急程序 如果在一般条件下并且按照推荐的方法使用材料，预计不必要执行应急程序。

6.2 环保预防措施

防止进入水道、下水道、地下室或封闭区域。

6.3 用于遏制/净化的方法和材料

遏制/净化措施 对于少量撒漏，戴手套并用纸巾吸附撒漏物。切勿将撒漏的材料冲刷到排水管道中予以处置。

6.4 其他各章的参考

请参阅第 8 章 - 接触控制/个人防护以及第 13 章 - 处置注意事项。

第 7 章：操作和贮存

7.1 用于安全操作的预防措施

操作 无需任何特殊操作。如果盒子断裂，避免接触撒漏的制剂。避免接触皮肤和眼睛。

7.2 包括任何不相容性的安全贮存条件

贮存 按产品标签予以贮存。远离不相容材料。上锁贮存。将容器/包装在阴凉、通风良好之处保持密闭。

7.3 特定最终用途

请参阅第1.2条 - 有关确定用途。

第 8 章：接触控制/个人防护

8.1 控制参数

接触限值/指南		
	结果	**OSHA**
甘油 (56-81-5)	TWAs	15 mg/m3 TWA（气雾，微粒总量）；5 mg/m3 TWA（气雾，可呼吸部分）
异硫氰酸胍	TWAs	5 mg/m3 TWA（以 CN 计） *以氰化物计*

8.2 接触控制

工程措施/控制 应当使用良好的通用通风设施。通风速率应当与环境相配。如果适用，使用工艺外罩、局部排气通风或其它工程控制设施，以保持空气中的浓度低于推荐的接触限值。如果尚未确定接触限值，就将空气中的浓度保持在可接受的水平。

个人防护装备

呼吸 遵守29 CFR 1910.134或欧洲标准EN 149中可见的OSHA呼吸器条例。如果超过接触限值或出现症状，就使用NIOSH/MSHA或欧洲标准EN 149认可的呼吸器。

眼睛/面部 佩戴防化学剂飞溅护目镜。

皮肤/身体 穿戴防护服。

环境接触控制 遵守厂区管理和废物处置最佳规范。

略语表
OSHA = 职业安全和健康管理局
TWA = 时间加权平均值根据8小时/天、40小时/周的接触量来确定

第 9 章：物理性质和化学性质

9.1 有关物理性质和化学性质的信息

材料描述			
外形	液体	外形/描述	微珠在盒中是白色固体成分；试剂是透明液体，其主要在水溶液中缓冲。成分无味。
颜色	白色/透明	气味	无味
气味阈值	数据缺乏		
一般性质			
沸点	100 ° C (212 ° F)	熔点/凝固点	0 ° C (32 ° F)
分解温度	数据缺乏	pH值	7至9 Lysis 制剂 #1 (GTC pH (3.7-4.1.)) Lysis 制剂 #2 (氢氧化钠 <1% pH 14)。
比重/相对密度	数据缺乏	水溶解度	数据缺乏
粘度	数据缺乏	易爆性质	数据缺乏
氧化性性质	数据缺乏		
挥发性			
蒸气压力	数据缺乏	蒸气密度	数据缺乏
蒸发速率	数据缺乏		
易燃性			
闪点	360 至 560 ° F（182.2222 至 293.3333 ° C）（结合剂）	爆炸上限	数据缺乏
爆炸下限	数据缺乏	自燃点	数据缺乏
易燃性（固体、气体）	数据缺乏		
环境方面			
辛醇/水分配系数	数据缺乏		

9.2 其他信息

未注明额外的物理和化学参数。

第 10 章：稳定性和反应性

10.1 反应性

在正常使用条件下，未知有危险反应。

10.2 化学稳定性

稳定

10.3 危险反应的可能性

不会发生危险的聚合反应。

10.4 应避免的情况

不相容的材料。热、与酸或漂白剂接触可释放非常有毒的气体。

10.5 不相容的材料

酸、氧化剂。

10.6 危险的分解产物

碳氧化物、钠氧化物。

第 11 章：毒物学信息

11.1 有关毒物学效应的信息

组成成分		
异硫氰酸胍 (5%至10%)	593-84-0	**急性毒性：**腹腔-小鼠 LD50 • 300 mg/kg
甘油 (1%至5%)	56-81-5	**急性毒性：**摄入/口服-大鼠 LD50 • 12600 mg/kg；*行为*：**全身麻醉**；*行为*：**肌无力**；*肝脏*：**其他变化**； **刺激：**眼睛-兔 • 500 mg 24 小时 • 轻度刺激；皮肤-兔 • 500 mg 24 小时 • 轻度刺激； **多剂量毒性：**摄入/口服-小鼠 TDLo • 560 g/kg 8 周-连续的；*肺、胸或呼吸系统*： **气管或支气管结构性或功能性变化**；摄入/口服-小鼠 TDLo • 2800 mg/kg 25 周-连续的；*皮肤和附属器官：其他*：**肿瘤**；*致瘤性*：**促进已知致瘤物的作用**； **诱变剂：**细胞遗传学分析 • 摄入/口服-大鼠 • 1 g/kg；DNA 抑制 •未报告途径-人类 • 淋巴细胞（体细胞） • 200 mmol/L； **生殖：**摄入/口服-大鼠 TDLo • 100 mg/kg（1D 男性）；*生殖效应：生育效应：* **植入后死亡率**； **致瘤物/致癌物：**摄入/口服-小鼠 TDLo • 87.5 g/kg 25 周-断续；*致瘤性*：**可疑的致肿瘤剂（按 RTECS 标准）**；*肺、胸或呼吸系统*：**肿瘤**；*致瘤性*：**促进已知致瘤物的作用**

GHS危险种类	危险类别
急性毒性	EU/CLP•缺乏数据 UN GHS•急性毒性 - 经口 5 - ATEmix（经口） = 5000 mg/kg OSHA HCS 2012•缺乏数据
皮肤腐蚀/刺激	EU/CLP•缺乏数据 UN GHS•轻度皮肤刺激 3 OSHA HCS 2012•缺乏数据
严重眼损伤/刺激	EU/CLP•缺乏数据 UN GHS•眼刺激 2 OSHA HCS 2012•眼刺激 2
皮肤过敏	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据
呼吸过敏	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据
吸入危险	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据
致癌性	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据
生殖细胞致突变性	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据
针对生殖的毒性	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据

GHS危险种类	危险类别
STOT-SE	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-RE	EU/CLP•缺乏数据 UN GHS•缺乏数据 OSHA HCS 2012•缺乏数据

潜在健康影响

吸入
急性（立即） 可能导致刺激。
慢性（缓发） 无可用数据
皮肤
急性（立即） 导致轻度的皮肤刺激。
慢性（缓发） 无可用数据
眼睛
急性（立即） 导致严重的眼睛刺激。
慢性（缓发） 无可用数据
摄入
急性（立即） 吞入时可能有害。
慢性（缓发） 无可用数据

略语表
LD = 致死剂量
TD = 毒性剂量

第 12 章：生态学信息

12.1 毒性
硫氰酸胍对水生生物有害。

12.2 持久性和降解性
材料数据缺失。

12.3 生物累积的潜力
材料数据缺失。

12.4 土壤中的移动性
材料数据缺失。

12.5 PBT及vPvB评估的结果
尚未进行 PBT 和 vPvB 评估。

12.6 其他不良效应
未发现研究成果。

第 13 章：处置注意事项

13.1 废物处理方法

产品废物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。
包装废弃物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。

13.2 其他信息

生物样本，包括废盒子，应以能够传播感染源对待。咨询您所在机构的环保废物处理人员有关妥善处置用过盒子和未用过试剂的信息。本材料可能会表现出联邦环保署（EPA）资源保护与回收法（RCRA）危险废料的特征，要求采用特定的处置规定。请查阅国家和当地法规，因为它们可能不同于联邦的处置法规。美国以外的机构应查阅其本国的危险废料处置规定。

第 14 章：运输信息

	14.1 UN编号	14.2 UN正式运输名称	14.3 运输危险分类	14.4 包装组	14.5 环境危害
DOT	NDA	未管制	NDA	NDA	NDA
TDG	NDA	未管制	NDA	NDA	NDA
IMO/IMDG	NDA	未管制	NDA	NDA	NDA
IATA/ICAO	NDA	未管制	NDA	NDA	NDA

14.6 用户特殊防护措施

未列明。

14.7 根据 MARPOL 73/78 的附录 II 和 IBC 准则散装运输

缺乏数据。

第 15 章：法规信息

15.1 针对特定物质或混合物的安全、卫生和环境条例/法规

SARA 危险性分类 急性、火灾

名录						
成分	CAS	加拿大DSL	加拿大NDSL	欧盟EINECS	欧盟ELNICS	TSCA
甘油	56-81-5	是	否	是	否	是
异硫氰酸胍	593-84-0	是	否	是	否	是

加拿大

劳动

加拿大 - 加拿大工作场所危险物质信息系统（WHMIS）- 物质分类

•甘油	56-81-5	根据 WHMIS 分类标准不受管制的产品
•异硫氰酸胍	593-84-0	未列出

加拿大 - 加拿大工作场所危险物质信息系统（WHMIS）- 组分披露列表

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

环境

加拿大 - 环境保护法 (CEPA) - 优先重点物质列表

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国

劳动

美国 - 职业安全与健康管理局 (OSHA) - 制程安全管理 - 高度危险化学品

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 职业安全与健康管理局 (OSHA) - 专门监管化学品

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

环境

美国 - CAA（清洁空气法）- 1990 年危险空气污染物

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 危险物质及其可报告数量

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 放射性核素及其可报告数量

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质 EPCRA 可报告数量

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质计划限制数量

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - 排放报告

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - PBT 化学品列表

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚

环境

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 致癌物清单

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 发育毒性

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 最大容许剂量水平 (MADL)

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 无显著风险级别 (NSRL)

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 女性

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 男性

•甘油	56-81-5	未列出
•异硫氰酸胍	593-84-0	未列出

15.2 化学安全评估

未进行化学安全评估。

第 16 章：其他信息

相关语词（代码及全文）

H302 - 如果吞入是有害的
H412 - 对水生生物有害，具有长期持续效应
EUH031 - 遇酸释放出有毒气体。

免责声明/责任声明

以上信息基于对于我们的可用数据，而且相信是正确的。由于对信息的应用可能会在超出我们控制的条件下和以我们所不熟悉的条件进行，因此我们对其使用的任何结果概不承担任何责任，而且收到此信息的所有人士均务必自行确定其特定应用条件下的效能、性能、防护和处置方法。未就信息所涵盖的材料、其准确性、因使用材料而获得的结果或与使用材料相关的危害作出任何明示或暗示的表示、担保或保证（包括对特定目的下适用性或适销性的担保）。操作或使用本材料应小心谨慎。以上信息以诚信提供，而且相信是准确的。截至签发日期，我们提供有关可预见材料操作的所有信息。然而，一旦发生与本品相关的恶性事故，本安全数据表却不是，而且也不旨在是向接受过适当训练人员咨询的替代。

略语表
NDA = 无可用数据

安全データシート
発効日:2016年9月
優先日付:2015年11月

セクション1:物質・混合物、および企業・事業の識別

1.1 製品識別子

製品名 **Xpert Trichomonas**
製品コード 900-0657; GXTV-10; GXTV-CE-10

1.2 物質や混合物の特定された関連用途、および推奨されない用途

特定された関連用途 研究用

1.3 安全データを提供した供給業者の詳細

製造業者 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US:techsupport@cepheid.com
電話(一般) 1 (888) 838-3222 - 米国オプション2
電話(一般) 1 (408) 541-4191 - 米国外

1.4 緊急電話番号

製造業者 1 (800) 424-9300 - CHEMTREC - 24時間緊急電話
製造業者 1 (703) 741-5500 - 米国外

セクション2:危険性識別

EU/EEC

準拠: 指令(EC)1272/2008 (CLP)/REACH 1907/2006 [453/2010による改訂]

2.1 物質や混合物の分類

CLP 次のSDSは研究所で使用されるため、最終製品でのみ使用されます。液体物質を含み、その一部は凍結乾燥粉末およびカートリッジやナルゲンボトルに含まれた試薬である場合があります。すべての試薬は、透明で無色の液体です。一部の物質の情報の開示の免除は、CLP 項目 1(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
未分類

2.2 ラベル要素

CLP

危険有害性情報 ラベル要素は必要ありません。

2.3 その他危険性

CLP 規定(EC) No. 1272/2008 (CLP) に準じて、本剤は危険物とみなされません。

UN GHS

準拠: UN 化学品の分類および表示に関する世界調和システム(GHS)

2.1 物質や混合物の分類

UN GHS

急性毒性 経口5
軽度の皮膚刺激3
眼刺激2

2.2 ラベル要素

UN GHS

警告

危険有害性情報

飲み込むと有害。
皮膚への軽度の刺激を引き起こす。
目に重度の刺激を引き起こす。

予防情報

予防

取り扱いの後、十分に洗う。
防護手袋／防護服／防護めがね／保護面を着用する。

応答

気分が悪い場合、毒物センターあるいは医師に連絡する。
皮膚に刺激が生じた場合:医師の助言／手当てを受ける。
目に入った場合:目に入った場合:数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目の刺激が続く場合:医師の助言／手当てを受ける。

2.3 その他危険性

UN GHS

危険化学品分類表示の世界調和システム(GHS)では、本製品は危険な物質と考慮されています。

米国(US)

準拠: OSHA 29 CFR 1910.1200 HCS

2.1 物質や混合物の分類

OSHA HCS 2012

眼刺激2

2.2 ラベル要素

OSHA HCS 2012

警告

危険有害性情報

目に重度の刺激を引き起こす。

予防情報

予防 取り扱いの後、十分に洗う。
防護手袋／防護服／防護めがね／保護面を着用する。

応答 目に入った場合:目に入った場合:数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目の刺激が続く場合:医師の助言／手当てを受ける。

2.3 その他危険性

OSHA HCS 2012 米国規定(29 CFR 1910.1200 - 危険有害性周知基準)に基づき、本製品は危険物とみなされます。

カナダ
準拠: WHMIS

2.1 物質や混合物の分類

WHMIS その他の毒性効果 - D2B

2.2 ラベル要素

WHMIS

その他の毒性効果 - D2B

2.3 その他危険性

WHMIS カナダでは、上述の製品は作業場にある危険物に関する情報システム (WHMIS)に基づき危険物とみなされています。

2.4 その他情報

次のSDSは研究所または臨床環境で使用されるため、最終製品用のみです。本製品は、液体試薬と凍結乾燥粉末を含むカートリッジです。示された危険性は、カーとっりじに含まれる試薬に基づいています。通常の使用中に、このカートリッジ内の試薬への暴露は予想されません。

セクション3:成分の組成・情報

3.1 物質

本剤は、材料区分を満たしません。

3.2 混合物

合成物					
化学名	**識別子**	**%**	**LD50/LC50**	**規定/指針に基づく分類**	**コメント**
グアニジンチオシアネート	**CAS:** 593-84-0 **EINECS:** 209-812-1	5%～10%	NDA	**UN GHS:**急性毒性 4(経口);皮膚のかゆみ 3; 目のかゆみ 2B;水生急性毒性3;水生慢性毒性3 **EU CLP:**急性毒性 4、H302;EUH031; 水生慢性毒性 3、H412 **OSHA HCS 2012:**急性毒性 4(経口);目のかゆみ 2B	NDA

合成物					
グリセロール	**CAS:** 56-81-5 **EC番号:** 200-289-5	1%～5%	摂取/経口-ラット LD50・12600 mg/kg	**UN GHS:**眼の刺激 2;皮膚の刺激 3 **EU CLP:**眼の刺激 2、H319 **OSHA HCS 2012:**眼の刺激 2	NDA

H-statementの全文については、第16節を参照してください。

セクション4:応急処置手段

4.1 応急措置手段

吸引

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。被災者を新鮮な空気がある場所に移す。呼吸困難の場合は酸素を供給する。被災者が物質を吸引した場合、口移し式人工呼吸を行ってはならない; 一方向バルブの付いたポケットマスクや、その他の適切な呼吸医療装置を使って人工呼吸を行う。被災者が呼吸していない場合は、人工呼吸を施す。

皮膚

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。軽度の皮膚との接触では、影響を受けていない皮膚に物質を広げないようにする。物質と接触した場合は、最低20分間、直ちに流水で皮膚を洗浄する。汚染した衣類を取り除いて隔離する。

目

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。物質と接触した場合は、最低20分間、直ちに流水で目を洗浄する。目の刺激が続く場合:医師の助言/手当てを受ける。

摂取

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。飲み込んだ場合は、水で口をゆすいでください(意識がある場合)。嘔吐を誘発しないでください。被災者が物質を摂取した場合は口移し式人工呼吸を行ってはならない。摂取した場合は直ちに医師の手当てを受ける。

4.2 もっとも重要な症状と影響、急性および遅発性

第十一項 毒性に関する情報を参照してください。

4.3 直ちに医学的配慮と特別治療を必要とする兆候

医師へのメモ

治療はすべて、患者の苦痛の兆候および症状に基づき行われる必要があります。本製品以外の物質に著しくさらされた可能性について考慮する必要があります。

セクション5:消化手段

5.1 消火剤

適切な消火剤 大規模火災:乾燥した化学品、二酸化炭素、耐アルコール泡消火剤、散水
小規模火災:乾燥した化学品、二酸化炭素、散水

不適切な消火剤 データなし

5.2 物質や混合物から発生する特別な危険

異常な火災と爆発の危険 炭素酸化物、硫黄酸化物、窒素酸化物の有毒な蒸気を放出することがあります。

有害な燃焼生物 データなし

5.3 消防士への助言

流出した状況では物質に直接接触する可能性があ るため、効果がない製造業者が推奨する 化学品防護服を着用する。
製造業者が推奨する化学品防護服を着用する。熱に対する保護は、ある程度、またはまったく提供されない。
陽圧自給式呼吸器(SCBA)を着用する。
小規模火災:危険を冒さずにできる場合は、火災区域から容器を移動させる動かす。

セクション6:漏出時の措置

6.1 人体に対する注意事項、保護具、および緊急時措置

人体に対する注意事項 カートリッジが破損した場合、これらの人体に対する予防措置が適用されます。適切な保護服を着用する。漏出した物質を通って歩かない。適切な保護服を着用せずに破損した容器または漏出した物質に触れてはならない。閉じ込められた場所を換気する。

応急措置 物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されない。

6.2 影響に対する注意事項

水路、下水道、地下室、囲まれた区域に流入するのを防ぐ。

6.3 閉じ込めと清掃の手段と物質

閉じ込めと清掃の手段 少量の流出の場合は、手袋を着用し、ペーパータオルで流出を吸収してください。流出した物質を排水溝に廃棄しないでください。

6.4 他のセクションへの言及

第八項 爆発管理/安全保護、および第十三項 廃棄時の注意事項を参照してください。

セクション7:取り扱いと保管

7.1 安全な取り扱いについての注意

取り扱い 特別な取扱いは必要ありません。カートリッジが破損した場合、漏出した試薬に触れないようにしてください。皮膚に付着したり、目に入らないようにしてください。

7.2 安全な保管の条件、不適合性を含む

保管 製品ラベルに従って保管してください。互換性をもたない物質から離す。鍵をかけて保管する。容器/パッケージをしっかりと密閉し、涼しく、風通しの良い場所に保管してください。

7.3 具体的な最終用途

セクション1.2 関連する使用方法に関する情報を参照してください。

セクション8:暴露管理・個人保護

8.1 管理パラメータ

曝露限度/ガイドライン		
	結果	**OSHA**
グリセロール (56-81-5)	TWAs	15 mg/m3 TWA(霧状、全微粒子);5 mg/m3 TWA(霧状、呼吸可能な分画)
グアニジンチオシアネート	TWAs	5 mg/m3 TWA (CNとして) *青酸化合物として*

8.2 曝露管理

工学的手段・管理 十分な通気を確保してください。通規率は状況に応じて適切に調整してください。該当する場合は、包囲装置、局所排気装置、またはその他のエンジニアリングコントロール装置を使って、空気中の粉塵レベルが推奨暴露限界を超えないようにしてください。暴露レベルが確定されていない場合は、許容範囲の粉塵量を維持してください。

個人用保護具

呼吸器官 OSHA 呼吸器規制に関しては、29 CFR 1910.134 または 欧州標準EN 149をご覧ください。暴露基準を超える場合、あるいは症状が発症した場合は、NIOSH/MSHA または 欧州標準EN 149 保護マスクをご使用ください。

目・顔面 化学物飛散防止ゴーグルを着用してください。

皮膚・人体 保護服を着用してください。

環境暴露管理 現場管理および廃棄物の取り扱いは十分注意して行ってください。

略語について
OSHA = 労働安全衛生局
TWA = 時間加重平均値は、8時間/1日、40時間/1週間の暴露に基づいた数値です。

セクション9:物理的および化学的特性

9.1 物理的および化学的特性

材料の説明			
物理的形状	液体	外観/記述	ビーズはカートリッジ内の白色固体の物質であり、試薬は、主に水溶液で緩衝された透明な液体です。物質は無臭です。
色	白色/透明	臭気	無臭
臭気限界	データ不足		
一般的性質			
沸騰点	100 ° C (212 ° F)	融解点・凝固点	0 ° C (32 ° F)
分解温度	データ不足	pH	7～9 溶解試薬 №1 (GTC pH (3.7～4.1))溶解試薬 №2 (水酸化ナトリウム <1% pH 14)。
比重・相対密度	データ不足	水溶性	データ不足
粘性	データ不足	爆発特性	データ不足
酸化特性:	データ不足		
揮発度			
蒸気圧	データ不足	蒸気密度	データ不足
蒸発速度	データ不足		
可燃性			
引火点	182.2222～293.3333 ° C (360～560 ° F) (結合試薬)	UEL	データ不足
LEL	データ不足	自己発火	データ不足
可燃性(固体、ガス)	データ不足		
環境曝露管理			
オクタノール・水分配係数	データ不足		

9.2 その他情報

その他に物理的および化学的パラメータの記載はありません。

セクション10:安定性と反応性

10.1 反応性

通常の使用において、危険反応は報告されていません。

10.2 化学安定性

安定

10.3 有害反応の可能性

危険物のポリメリゼーションは発生しません。

10.4 回避すべき条件

不適合物質。熱、酸や漂白剤に触れると、非常に有害なガスを放出する場合があります。

10.5 不適合物質

酸、酸化試薬。

10.6 有害分解性生物

炭化酸化物、ナトリウム酸化物。

セクション11:毒性情報

11.1 毒性効果

成分		
グアニジンチオシアネート(5%～10%)	593-84-0	**急性毒性:** 腹腔内-マウス LD50・300 mg/kg
グリセロール(1%～5%)	56-81-5	**急性毒性:** 摂取/経口-ラット LD50・12600 mg/kg; *行動*: **全身麻酔薬**; *行動*: **筋力低下**; *肝臓*: **その他の変化**; **刺激:** 目-ウサギ・500 mg 24時間・軽度の炎症; 皮膚-ウサギ・500 mg 24時間・軽度の炎症; **複数用量毒性:** 摂取/経口-マウス TDLo・560 g/kg 8週間-継続的; *肺、胸部または呼吸*: **気管または気管支の構造または機能の変化**; 摂取/経口-マウス TDLo・2800 mg/kg 25 週間-継続的; *皮膚および付属器官:その他*: **腫瘍**; *腫瘍形成*: **既知の発癌物質の活性を促進する**; **変異原:** 細胞遺伝学的解析・摂取/経口-ラット・1 g/kg; DNA阻害・報告されていない経路-ヒト・リンパ球(体細胞)・200 mmol/L; **生殖:** 摂取/経口-ラット TDLo・100 mg/kg(1Dオス); *生殖への影響:生殖能力への影響*: **移植後の死亡率**; **腫瘍形成/発がん物質:** 摂取/経口-マウス TDLo・87.5 g/kg 25週間-間欠的; *腫瘍形成*: **RTECS基準によるとあいまいな腫瘍形成剤**; *肺、胸部または呼吸*: **腫瘍**; *腫瘍形成*: **既知の発癌物質の活性を促進する**

GHS特性	分類
急性毒性	EU/CLP-データ不足 UN GHS-急性毒性 - 経口5 - ATEmix(経口)=5000 mg/kg OSHA HCS 2012-データ不足
皮膚の腐食・炎症	EU/CLP-データ不足 UN GHS-軽度の皮膚の炎症 3 OSHA HCS 2012-データ不足
重度の目の損傷・炎症	EU/CLP-データ不足 UN GHS-目の炎症 2 OSHA HCS 2012-目の炎症 2
皮膚感作性	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足
呼吸器感作性	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足
吸引有害性	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足
発癌性	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足

GHS特性	分類
生殖細胞変異原性	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足
生殖毒性	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足
STOT-SE	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足
STOT-RE	EU/CLP-データ不足 UN GHS-データ不足 OSHA HCS 2012-データ不足

考えられる健康への影響

吸引
急性(即座) 過敏症が生じる場合があります。
慢性(遅発性) データなし
皮膚
急性(即座) 皮膚に軽度の刺激を引き起こします。
慢性(遅発性) データなし
目
急性(即座) 目に重度の刺激を引き起こします。
慢性(遅発性) データなし
摂取
急性(即座) 飲み込むと有害の可能性。
慢性(遅発性) データなし

略語について
LD = 致死量
TD = 中毒量

セクション12:生態学的情報

12.1 毒性
チオシアン酸グアニジンは、水生生物に有害。

12.2 持続性と分解性
実態データが不足しています

12.3 生体内蓄積能
実態データが不足しています

12.4 土壌中移動性
実態データが不足しています

12.5 PBTとvPvB評価の結果

PBTおよび vPvBアセスメントは行われていません。

12.6 その他有害影響

そのような研究結果はありません。

セクション13:廃棄上の注意

13.1 廃棄物処理手段

製品廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

包装廃棄物 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

13.2 その他情報

使用済みカートリッジなどの生物試料は、感染物質を伝染する能力があるものとして取り扱われる必要があります。使用済みカートリッジと未使用の試薬の適切な廃棄方法については、機関の環境廃棄物担当員に相談してください。この資料は、特別な廃棄要件をもつ連邦EPA資源保全再生法(RCRA)の危険廃棄物の特性を示している場合があります。州と地方の規則については、連邦の廃棄方法の規則と異なる場合があるので、ご確認ください。米国外の機関では、その国の危険廃棄物処理方法の要件をご確認ください。

セクション14:輸送情報

	14.1 UN番号	14.2 UN 正式輸送品目名	14.3 輸送有害性等級	14.4 包装等級	14.5 環境有害性
DOT	NDA	規制なし	NDA	NDA	NDA
TDG	NDA	規制なし	NDA	NDA	NDA
IMO/IMDG	NDA	規制なし	NDA	NDA	NDA
IATA/ICAO	NDA	規制なし	NDA	NDA	NDA

14.6 ユーザーに対する特別予防装置

指定なし。

14.7 MARPOL 73/78の付属書IIとIBCコードに則ったバルク輸送

データ不足。

セクション15:規制情報

15.1 物質や混合物についての具体的な安全、健康、環境規制・法律

SARA危険分類 急性、火災

在庫						
成分	CAS	カナダDSL	カナダNDSL	EU EINECS	EU ELNICS	TSCA
グリセロール	56-81-5	あり	なし	あり	なし	あり
グアニジンチオシアネート	593-84-0	あり	なし	あり	なし	あり

カナダ

作業

カナダ - WHMIS - 物質の分類

·グリセロール	56-81-5	WHMIS分類基準によると非管理製品
·グアニジンチオシアネート	593-84-0	掲載外

カナダ - WHMIS - 成分開示リスト

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

環境

カナダ - CEPA - 優先物質リスト

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国

作業

米国 - OSHA - プロセス安全管理 - 非常に危険有害な化学品

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - OSHA - 特異制御化学物質

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

環境

米国 - CAA (大気汚染防止法) - 1990 有害大気汚染物質

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 有害危険物質および報告基準量

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 放射性核種および報告義務量

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第302項-極めて有害な物質EPCRAの報告義務量

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第302項-極めて有害な物質TPQ

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第313項-排気量レポート

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - CERCLA/SARA - 第313項-排出報告

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - カリフォルニア

環境

米国 - カリフォルニア - 州住民投票事項65 - 発がん性物質リスト

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - カリフォルニア - 州住民投票事項65 - 発達毒性

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - カリフォルニア - 州住民投票事項65 - 最大許容レベル(MADL)

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - カリフォルニア - 州住民投票事項65 - 無リスク(安全)摂取量(NSRL)

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - カリフォルニア - 州住民投票事項65 - 生殖毒性- 女性

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

米国 - カリフォルニア - 州住民投票事項65 - 生殖毒性- 男性

·グリセロール	56-81-5	掲載外
·グアニジンチオシアネート	593-84-0	掲載外

15.2 化学物質安全評価

化学的安全評価は実施されていません。

セクション16:その他情報

関連表現(コードと全文)

H302 – 飲み込むと有害。
H412 – 水生生物に対して有害で、影響が長期に及ぶ。
EUH031 – 酸との接触によって毒性ガスが放出される。

免責条項/責任声明

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略語について
NDA = 該当データなし。

Safety Data Sheet
Effective Date: February, 2020
Supersedes Date: July, 2016

Xpert Urine Collection Kit
Xpert CT/NG Urine Specimen Collection Kit

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifier

Product Name	**Xpert Urine Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit**
Product Code	CT/NGURINE-50; URINE/A-50

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Relevant Identified Use(s)	Laboratory use

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States www.cepheid.com US: techsupport@cepheid.com
Telephone (General)	1 (888) 838-3222 - US Option 2
Telephone (General)	1 (408) 541-4191 - Outside of the US
Supplier	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden www.cepheidinternational.com EU: support@cepheideurope.com
Telephone (General)	+33 563 825 319

1.4 Emergency Telephone Number

Manufacturer	+ 1 (800) 535-5053 - INFOTRAC - 24 hr Emergency
Manufacturer	+ 1 (352) 323-3500- Outside of the US

Section 2: Hazards Identification

EU/EEC

According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the Substance or Mixture

CLP	The following SDS is for the final finished product only as used in the laboratory. It contains liquid components, some of which are in freeze-dried powders and reagents which are contained in the cartridge and in a Nalgene bottle. All reagents are clear, colorless liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2). Eye Irritation 2 - H319

2.2 Label Elements

CLP

WARNING

Hazard Statements H319 - Causes serious eye irritation

Precautionary Statements

Prevention P264 - Wash thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Response P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3 Other Hazards

CLP According to Regulation (EC) No. 1272/2008 (CLP) this material is considered hazardous.

UN GHS Revision 3

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

2.1 Classification of the Substance or Mixture

UN GHS

Acute Toxicity Oral 5
Eye Irritation 2
Hazardous to the aquatic environment Acute 1
Hazardous to the aquatic environment Chronic 1

2.2 Label Elements

UN GHS

WARNING

Hazard Statements

May be harmful if swallowed
Causes serious eye irritation
Very toxic to aquatic life
Very toxic to aquatic life with long lasting effects

Precautionary Statements

Prevention

Wash thoroughly after handling.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection.

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Call a POISON CENTER or doctor/physician if you feel unwell.
Collect spillage.

Storage/Disposal Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

2.3 Other Hazards

UN GHS According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous.

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the Substance or Mixture

OSHA HCS 2012 Eye Irritation 2

2.2 Label Elements

OSHA HCS 2012

WARNING

Hazard Statements Causes serious eye irritation

Precautionary Statements

Prevention Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

2.3 Other Hazards

OSHA HCS 2012 Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

Canada
According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS Other Toxic Effects - D2B

2.2 Label Elements

WHMIS

Other Toxic Effects - D2B

2.3 Other Hazards

WHMIS In Canada, the product mentioned above is considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).

2.4 Other Information

All other reagents, beads, and other constituents are at concentrations less than 1% in the mixture or not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

Section 3: Composition/Information on Ingredients

3.1 Substances

Material does not meet the criteria of a substance.

3.2 Mixtures

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Ammonium chloride	**CAS:** 12125-02-9 **EC Number:** 235-186-4 **EU Index:** 017-014-00-8	20% TO 30%	Ingestion/Oral-Rat LD50 • 1650 mg/kg	**EU CLP:** Annex VI, Table 3.1: Acute Tox. 4 *, H302; Eye Irrit. 2, H319 **UN GHS Revision 3:** Acute Tox. 4 (orl); Eye Irrit. 2; Aquatic Acute 1; Aquatic Chronic 1 **OSHA HCS 2012:** Acute Tox. 4 (orl); Eye Irrit. 2	NDA
Potassium carbonate	**CAS:**584-08-7 **EC Number:** 209-529-3	1% TO 5%	Ingestion/Oral-Rat LD50 • 1870 mg/kg	**EU CLP:** Acute Tox. 4, H302 **UN GHS Revision 3:** Acute Tox. 4 (orl); Eye Irrit. 2B **OSHA HCS 2012:** Acute Tox. 4 (orl); Eye Irrit. 2B	NDA

See Section 16 for full text of H-statements.

Section 4: First Aid Measures

4.1 Description of First Aid Measures

Inhalation First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move victim to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing.

Skin First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. For minor skin contact, avoid spreading material on unaffected skin. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Remove and isolate contaminated clothing.

Eye First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. If swallowed, rinse mouth with water (only if the person is conscious) Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Obtain medical attention immediately if ingested.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Refer to Section 11 - Toxicological Information.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician	All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	LARGE FIRES: Dry chemical, CO2, alcohol-resistant foam or water spray. SMALL FIRES: Dry chemical, CO2 or water spray.
Unsuitable Extinguishing Media	No data available

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	May emit toxic vapors of carbon oxides, nitrogen oxides.
Hazardous Combustion Products	No data available

5.3 Advice for Firefighters

Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.
Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.
Wear positive pressure self-contained breathing apparatus (SCBA).
SMALL FIRES: Move containers from fire area if you can do it without risk.

Section 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions	In the event a cartridge is broken these personal precautions are applicable. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate enclosed areas.
Emergency Procedures	No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

6.3 Methods and Material for Containment and Cleaning Up

Containment/ Clean-up Measures	For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.

6.4 Reference to Other Sections

Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7: Handling and Storage

7.1 Precautions for Safe Handling

Handling — No special handling necessary. If cartridge is broken avoid contact with spilled reagents. Avoid contact with skin and eyes.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Storage — Store according to product labeling. Keep container/package tightly closed in a cool, well-ventilated place. Keep away from incompatible materials.

7.3 Specific End Use(s)

Refer to Section 1.2 - Relevant identified uses.

Section 8: Exposure Controls/Personal Protection

8.1 Control Parameters

Exposure Limits/Guidelines				
	Result	**ACGIH**	**NIOSH**	**OSHA**
Ammonium chloride (12125-02-9)	STELs	20 mg/m3 STEL (fume)	20 mg/m3 STEL (fume)	Ammonium chloride (12125-02-9)
	TWAs	10 mg/m3 TWA (fume)	10 mg/m3 TWA (fume)	Not established

8.2 Exposure Controls

Engineering Measures/Controls — Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory — Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face — Wear chemical splash safety goggles.

Skin/Body — In laboratory setting, wear gloves and lab coat at a minimum to minimize skin contact.

Environmental Exposure Controls — Follow best practice for site management and disposal of waste.

Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygiene
NIOSH = National Institute of Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
STEL = Short Term Exposure Limits are based on 15-minute exposures
TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Reagents are clear, colorless liquids with no odor which are primarily buffered in aqueous solutions.
Color	Clear	Odor	Odorless
Odor Threshold	Data lacking		
General Properties			
Boiling Point	100 °C(212 °F)	Melting Point/Freezing Point	0 °C(32 °F)
Decomposition Temperature	Data lacking	pH	8 to 8.3 (solids and other liquid reagents)
Specific Gravity/Relative Density	Data lacking	Water Solubility	Data lacking
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Data lacking	Vapor Density	Data lacking
Evaporation Rate	Data lacking		
Flammability			
Flash Point	Data lacking	UEL	Data lacking
LEL	Data lacking	Autoignition	Data lacking
Flammability (solid, gas)	Data lacking		
Environmental			
Octanol/Water Partition Coefficient	Data lacking		

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical Stability

Stable

10.3 Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4 Conditions to Avoid

Heat, moisture (affecting product quality)

10.5 Incompatible Materials

Acids, oxidizing agents.

10.6 Hazardous Decomposition Products

Carbon oxides, potassium oxides.

Section 11: Toxicological Information

11.1 Information on Toxicological Effects

Components		
Ammonium chloride (20% TO 30%)	12125-02-9	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 1650 mg/kg; **Irritation:** Eye-Rabbit • 100 mg • Severe irritation
Potassium carbonate (1% TO 5%)	584-08-7	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 1870 mg/kg; **Multi-dose Toxicity:** Inhalation-Rat TCLo • 43 mg/m³ 17 Week(s); *Cardiac*:**EKG changes not diagnostic of above**; *Kidney, Ureter, and Bladder*:**Other changes in urine composition**; *Nutritional and Gross Metabolic:Changes in Chemistry or Temperature*: **K**; **Mutagen:** Unscheduled DNA synthesis • Ingestion/Oral-Rat • 504 g/kg 4 Week(s)-Continuous

GHS Properties	Classification
Acute Toxicity	**EU/CLP**•Data lacking **UN GHS 3**•Acute Toxicity - Oral 5 - ATEmix (oral) = 4795 mg/kg **OSHA HCS 2012**•Data lacking
Skin Corrosion/Irritation	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Serious Eye Damage/Irritation	**EU/CLP**•Eye Irritation 2 **UN GHS 3**•Eye Irritation 2 **OSHA HCS 2012**•Eye Irritation 2
Skin Sensitization	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Respiratory Sensitization	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Aspiration Hazard	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Carcinogenicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Germ Cell Mutagenicity	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
Toxicity for Reproduction	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-SE	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-RE	**EU/CLP**•Data lacking **UN GHS 3**•Data lacking **OSHA HCS 2012**•Data lacking

Potential Health Effects

Inhalation
Acute (Immediate) No data available
Chronic (Delayed) No data available
Skin
Acute (Immediate) No data available
Chronic (Delayed) No data available
Eye
Acute (Immediate) Causes serious eye irritation.
Chronic (Delayed) No data available
Ingestion
Acute (Immediate) May be harmful if swallowed.
Chronic (Delayed) No data available

Key to abbreviations
LD = Lethal Dose
TC = Toxic Concentration

Section 12: Ecological Information

12.1 Toxicity

	CAS	
Xpert Urine Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit	NDA	**Aquatic Toxicity-Fish:** 4 Day(s) LC50 *Atlantic Silverside* 0.14 mg/L Comments: Ammonium chloride (12125-02-9) 30 Day(s) NOEC *Channel Catfish* 0.006 mg/L Comments: Ammonium chloride (12125-02-9) **Aquatic Toxicity-Crustacea:** 2 Day(s) EC50 *Ostracod* 0.075-0.126 mg/L Comments: Ammonium chloride (12125-02-9) 21 Day(s) NOEC *Water flea* 0.05 mg/L Comments: Ammonium chloride (12125-02-9) **Aquatic Toxicity-Algae and Other Aquatic Plant(s):** 3 Day(s) EC50 *Algae Neptune's Necklace* 0.04-0.1 mg/L Comments: Ammonium chloride (12125-02-9)

12.2 Persistence and Degradability

Material data lacking.

12.3 Bioaccumulative Potential

Material data lacking.

12.4 Mobility in Soil

Material data lacking.

12.5 Results of PBT and vPvB Assessment

No PBT and vPvB assessment has been conducted.

12.6 Other Adverse Effects

No studies have been found.

Section 13: Disposal Considerations

13.1 Waste Treatment Methods

Product Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging Waste Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13.2 Other Information

Biological specimens, including used cartridges, should be treated as capable of transmitting infectious agents. Consult your institution's environmental waste personnel on proper disposal of used cartridges and unused reagents. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions outside the USA should check their country hazardous waste disposal requirements.

Section 14: Transport Information

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Transport Hazard Class(es)	14.4 Packing Group	14.5 Environmental Hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
TDG	UN3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ammonium chloride)	9	III	NDA
IMO/IMDG	UN3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ammonium chloride)	9	III	NDA
IATA/ICAO	UN3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ammonium chloride)	9	III	NDA

14.6 Special Precautions for User

None specified.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Data lacking.

Section 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SARA Hazard Classifications Acute

Inventory						
Component	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Ammonium chloride	12125-02-9	Yes	No	Yes	No	Yes
Potassium carbonate	584-08-7	Yes	No	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

•Potassium carbonate	584-08-7	D2B, E
•Ammonium chloride	12125-02-9	D2B

Canada - WHMIS - Ingredient Disclosure List

•Potassium carbonate	584-08-7	1%
•Ammonium chloride	12125-02-9	1%

Environment

Canada - CEPA - Priority Substances List

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	5000 lb final RQ; 2270 kg final RQ

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List		
•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Potassium carbonate	584-08-7	Not Listed
•Ammonium chloride	12125-02-9	Not Listed

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16: Other Information

Relevant Phrases (code & full text)

H302 - Harmful if swallowed

Revision Date 01/March/2016

Preparation Date 01/August/2014

Disclaimer/ Statement of Liability The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections, and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel. Please provide disclaimer.

Key to abbreviations
NDA = No data available

Fiche signalétique
Date d'entrée en vigueur : Février 2020
Remplace la date : Juillet 2016

Kit de prélèvement d'échantillon d'urine Xpert
Kit de prélèvement d'échantillon urinaire Xpert CT/NG

Section 1 : Identification de la substance/du mélange et de la compagnie/entreprise

1.1 Identifiant de produit

Nom du produit **Kit de prélèvement d'échantillon d'urine Xpert, Kit de prélèvement d'échantillon d'urine Xpert CT/NG**

Code de produit CT/NGURINE-50 ; URINE/A-50

1.2 Utilisations pertinentes identifiées de la substance ou du mélange et utilisations contre-indiquées

Utilisation(s) pertinente(s) identifiée(s) Utilisation en laboratoire

1.3 Coordonnées du fournisseur de la fiche de données de sécurité (FDS)

Fabricant Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
États-Unis
www.cepheid.com
États-Unis : techsupport@cepheid.com

Téléphone (général) 1 (888) 838-3222 - États-Unis Choix 2

Téléphone (général) 1 (408) 541-4191 - En dehors des États-Unis

Fournisseur Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Suède
www.cepheidinternational.com
UE : support@cepheideurope.com

Téléphone (général) +33 563 825 319

1.4 Numéro de téléphone d'urgence

Fabricant + 1 (800) 535-5053 - INFOTRAC - Urgences 24 h/24

Fabricant + 1 (352) 323-3500- En dehors des États-Unis

Section 2 : Identification des risques

EU/EEC

Selon : Règlement (CE) N° 1272/2008 (CLP)/REACH 1907/2006 [modifié par le 453/2010]

2.1 Classification de la substance ou mélange

CLP La fiche de données de sécurité (FDS) suivante concerne uniquement le produit fini final, tel qu'utilisé au laboratoire. Il contient des composants liquides dont certains sont des poudres lyophilisées et des réactifs qui sont contenus dans la cartouche et dans un flacon en Nalgène. Tous les réactifs sont des liquides incolores et limpides. Les exemptions à la divulgation des informations concernant certains composants sont conformes aux réglementations CLP Article 1(5)(d) et 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Irritation oculaire 2 - H319

2.2 Éléments de l'étiquette

CLP

ATTENTION

Mentions de danger	H319 - Provoque une irritation oculaire grave
Mises en garde	
Prévention	P264 - Se laver soigneusement après manipulation. P280 - Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
Réponse	P305+P351+P338 - EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer. P337+P313 - Si l'irritation oculaire persiste : consulter un médecin.

2.3 Autres dangers

CLP	Selon le règlement (CE) N° 1272/2008 (CLP), ce produit est considéré dangereux.

SGH ONU Révision 3

Selon : ONU - Système général harmonisé de classification et d'étiquetage des produits chimiques (SGH) : Troisième édition révisée

2.1 Classification de la substance ou mélange

SGH ONU	Toxicité aiguë par voie orale 5 Irritation oculaire 2 Dangereux pour le milieu aquatique - Toxicité aiguë 1 Dangereux pour le milieu aquatique - Toxicité chronique 1

2.2 Éléments de l'étiquette

SGH ONU

ATTENTION

Mentions de danger	Nocif en cas d'ingestion Provoque une irritation oculaire grave Très toxique pour la vie aquatique Très toxique pour la vie aquatique avec des effets durables
Mises en garde	
Prévention	Se laver soigneusement après manipulation. Éviter le rejet dans l'environnement. Porter des gants de protection/des vêtements de protection/une protection oculaire/une protection faciale.

Réponse	EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer. Si l'irritation oculaire persiste : consulter un médecin. Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise. Recueillir le déversement.
Stockage/Mise au rebut	Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

2.3 Autres dangers

SGH ONU	Selon le Système général harmonisé de classification et d'étiquetage (SGH), ce produit est considéré dangereux.

États-Unis (É.-U.)
Selon : OSHA 29 CFR 1910.1200 HCS

2.1 Classification de la substance ou mélange

OSHA HCS 2012	Irritation oculaire 2

2.2 Éléments de l'étiquette

OSHA HCS 2012

ATTENTION

Mentions de danger	Provoque une irritation oculaire grave
Mises en garde	
Prévention	Se laver soigneusement après manipulation. Porter des gants de protection/des vêtements de protection/une protection oculaire/une protection faciale.
Réponse	EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et que cela est facile à faire. Continuer à rincer. Si l'irritation oculaire persiste : consulter un médecin.

2.3 Autres dangers

OSHA HCS 2012	En vertu des réglementations des États-Unis (29 CFR 1910.1200 - Norme de communication des dangers), ce produit est considéré dangereux.

Canada
Selon : WHMIS

2.1 Classification de la substance ou mélange

WHMIS	Autres effets toxiques - D2B

2.2 Éléments de l'étiquette

WHMIS

Autres effets toxiques - D2B

2.3 Autres dangers

WHMIS

Au Canada, le produit mentionné ci-dessus est considéré dangereux selon le Système d'information sur les matières dangereuses utilisées au travail (SIMDUT).

2.4 Autres informations

Tous les autres réactifs, les billes et autres constituants sont à des concentrations inférieures à 1 % dans le mélange ou ne sont pas considérés dangereux selon la réglementation américaine sur la communication des dangers (29 CFR 1910.1200), selon les directives de l'UE concernant la classification et l'étiquetage des substances et des mélanges, ou selon le système international d'harmonisation pour la classification et l'étiquetage des substances ou des mélanges.

Section 3 : Composition/informations sur les ingrédients

3.1 Substances

La matière ne répond pas aux critères d'une substance.

3.2 Mélanges

Composition					
Nom chimique	**Identifiants**	**%**	**LD50/LC50**	**Classifications selon réglementation/directive**	**Commentaires**
Chlorure d'ammonium	**CAS :** 12125-02-9 **Numéro CE :** 235-186-4 **Index UE :** 017-014-00-8	20 % À 30 %	Ingestion/voie orale-Rat LD50 • 1650 mg/kg	**EU CLP :** Annexe VI, tableau 3.1 : Tox. aiguë 4 *, H302 ; irrit. yeux 2, H319 **SGH ONU Revision 3 :** Tox. aiguë 4 (orl) ; Irrit. yeux 2 ; Aquatique Aigu 1 ; Aquatique Chronique 1 **OSHA HCS 2012 :** Tox. aiguë 4 (orl) ; Irrit. yeux 2	ADD
Carbonate de potassium	**CAS :** 584-08-7 **Numéro CE :** 209-529-3	1 % À 5 %	Ingestion/voie orale-Rat LD50 • 1870 mg/kg	**EU CLP :** Tox. aiguë 4, H302 **SGH ONU Révision 3 :** Tox. aiguë 4 (orl) ; Irrit. yeux 2B **OSHA HCS 2012 :** Tox. aiguë 4 (orl) ; Irrit. yeux 2B	ADD

Voir la section 16 pour le texte complet des déclarations H.

Section 4 : Mesures de premier secours

4.1 Description des premiers soins

Inhalation

Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. Déplacer la victime à l'air frais. Administrer de l'oxygène si la respiration est difficile. Ne pas faire de bouche-à-bouche si la victime a inhalé la substance ; pratiquer la respiration artificielle à l'aide d'un masque de poche doté d'une valve unidirectionnelle ou d'un autre dispositif médical respiratoire approprié. Pratiquer la respiration artificielle si la victime ne respire pas.

Peau	Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact cutané mineur, éviter de répandre la matière sur la peau non affectée. En cas de contact avec la substance, rincer immédiatement la peau à l'eau courante pendant au moins 20 minutes. Retirer et isoler les vêtements contaminés.
Yeux	Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas de contact avec la substance, rincer immédiatement les yeux à l'eau courante pendant au moins 20 minutes. Si l'irritation oculaire persiste : consulter un médecin.
Ingestion	Les premiers secours ne devraient pas s'avérer nécessaires si le produit est utilisé dans des conditions normales et selon les recommandations. En cas d'ingestion, rincer la bouche avec de l'eau (seulement si la victime est consciente). NE PAS faire vomir. Ne pas faire de bouche-à-bouche si la victime a ingéré la substance. Consulter immédiatement un médecin en cas d'ingestion.

4.2 Symptômes et effets les plus importants, aigus et différés

Voir la section 11 - Information toxicologique.

4.3 Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires

Notes pour le médecin	Tous les traitements doivent être basés sur les signes et symptômes de détresse observés chez le patient. Il faut envisager la possibilité d'une surexposition à d'autres matières que ce produit.

Section 5 : Mesures de lutte contre l'incendie

5.1 Agents extincteurs

Agent extincteur convenable	INCENDIES MAJEURS : poudre sèche, CO2, mousse antialcool ou eau pulvérisée. INCENDIES MINEURS : poudre sèche, CO2, ou eau pulvérisée.
Agent extincteur inapproprié	Aucune donnée disponible

5.2 Dangers particuliers résultant de la substance ou du mélange

Dangers inhabituels d'incendie et d'explosion	Peut émettre des vapeurs toxiques d'oxydes de carbone, et d'oxydes d'azote.
Produits de combustion dangereux	Aucune donnée disponible

5.3 Conseils aux pompiers

Les vêtements structurels de protection des pompiers fournissent une protection limitée UNIQUEMENT en cas d'incendie ; ils ne sont pas efficaces dans les cas de déversement où le contact direct avec la substance est possible.
Porter des vêtements de protection chimique spécifiquement recommandés par le fabricant. Ceux-ci peuvent fournir peu ou pas de protection thermique.
Porter un appareil respiratoire autonome à pression positive (ARA).
INCENDIES MINEURS : enlever les conteneurs de la zone d'incendie si vous pouvez le faire sans risque.

Section 6 : Mesures en cas de fuite accidentelle

6.1 Précautions individuelles, équipement de protection et mesures d'urgence

Précautions individuelles	Dans le cas où une cartouche est percée, ces précautions individuelles s'appliquent. Porter les vêtements de protection appropriés. Ne pas marcher à travers la matière déversée. Ne pas toucher les conteneurs endommagés ou la matière déversée sauf en cas de port de vêtements de protection appropriés. Ventiler les espaces clos.
Mesures d'urgence	Aucune procédure d'urgence ne devrait s'avérer nécessaire si le produit est utilisé dans des conditions normales et selon les recommandations.

6.2 Précautions environnementales

Prévenir la pénétration dans les cours d'eau, les égouts, les sous-sols ou les endroits confinés.

6.3 Méthodes et matériaux de confinement et de nettoyage

Mesures de confinement/de nettoyage	Pour les petits déversements, porter des gants et absorber la matière déversée avec une serviette en papier. Ne pas jeter la matière déversée dans les égouts.

6.4 Référence à d'autres sections

Voir la section 8 - Contrôles de l'exposition/protection individuelle, ainsi que la section 13 - Considérations de mise au rebut.

Section 7 : Manutention et stockage

7.1 Précautions pour une manutention sans danger

Manutention	Aucune manipulation spéciale n'est nécessaire. Si une cartouche est percée, éviter tout contact avec les réactifs déversés. Éviter tout contact avec la peau et les yeux.

7.2 Conditions de sécurité du stockage, y compris toutes incompatibilités

Stockage	Stocker conformément à l'étiquetage des produits. Conserver le conteneur/emballage hermétiquement fermé dans un endroit frais et bien aéré. Tenir à l'écart des matières incompatibles.

7.3 Utilisation(s) finale(s) spécifique(s)

Voir la section 1.2 - Utilisations pertinentes identifiées.

Section 8 : Contrôles de l'exposition/protection individuelle

8.1 Paramètres de contrôle

Limites d'exposition/Lignes directrices			
	Résultat	**ACGIH**	**NIOSH**
Chlorure d'ammonium (12125-02-9)	STELs	20 mg/m3 STEL (fumée)	20 mg/m3 STEL (fumée)
	TWA	10 mg/m3 TWA (fumée)	10 mg/m3 TWA (fumée)

8.2 Contrôles d'exposition

Mesures/contrôles techniques
Une bonne ventilation générale doit être utilisée. Les débits de ventilation doivent être adaptés aux conditions. Le cas échéant, utiliser des enceintes d'isolement, une ventilation aspirante locale ou d'autres moyens techniques pour maintenir les concentrations atmosphériques en dessous des limites d'exposition recommandées. Si les limites d'exposition n'ont pas été établies, maintenir les concentrations atmosphériques à un niveau acceptable.

Équipement de protection individuelle

Respiratoire
Suivre les réglementations de l'OSHA relatives aux appareils respiratoires définies dans 29 CFR 1910.134 ou la norme européenne EN 149. Utiliser un appareil respiratoire approuvé par le NIOSH/MSHA ou la norme européenne EN 149 si les limites d'exposition sont dépassées ou des symptômes apparaissent.

Yeux/visage
Porter des lunettes anti-éclaboussures contre les produits chimiques.

Peau/corps
En environnement de laboratoire, porter au minimum des gants et une blouse de laboratoire afin de minimiser le contact avec la peau.

Contrôle d'exposition lié à la protection de l'environnement
Suivre les bonnes pratiques pour la gestion de site et l'élimination des déchets.

Clef aux abréviations
ACGIH = Conférence américaine des hygiénistes industriels gouvernementaux
NIOSH = Institut national pour la sécurité et la santé au travail
OSHA = Administration de la sécurité et de la santé au travail
STEL = Les limites d'exposition à court terme sont basées sur des expositions de 15 minutes
TWA = Les moyennes pondérées dans le temps sont basées sur des expositions de 8 h/jour, 40 h/semaine

Section 9 : Propriétés physiques et chimiques

9.1 Informations sur les propriétés physiques et chimiques

Description de la matière			
Forme physique	Liquide	Apparence/Description	Les réactifs sont des liquides incolores et limpides, sans odeur, qui sont principalement tamponnés dans des solutions aqueuses.
Couleur	Limpide	Odeur	Inodore
Seuil d'odeur	Manque de données		
Propriétés générales			
Point d'ébullition	100 °C (212 °F)	Point de fusion/Point de congélation	0 °C (32 °F)
Température de décomposition	Manque de données	pH	8 à 8,3 (solides et autres réactifs liquides)
Densité spécifique/relative	Manque de données	Solubilité dans l'eau	Manque de données
Viscosité	Manque de données	Propriétés explosives	Manque de données
Propriétés comburantes :	Manque de données		
Volatilité			
Pression de vapeur	Manque de données	Densité de vapeur	Manque de données
Taux d'évaporation	Manque de données		
Inflammabilité			
Point d'éclair	Manque de données	LSE	Manque de données
LIE	Manque de données	Auto-inflammation	Manque de données
Inflammabilité (solide, gaz)	Manque de données		
Environnemental(e)			
Coefficient de partage octanol/eau	Manque de données		

9.2 Autres informations

Aucun paramètre physique ou chimique supplémentaire noté.

Section 10 : Stabilité et réactivité

10.1 Réactivité

Pas de réactions dangereuses connues dans des conditions normales d'utilisation.

10.2 Stabilité chimique

Stable

10.3 Possibilité de réactions dangereuses

Il ne se produira pas de polymérisation dangereuse.

10.4 Situations à éviter

Chaleur, humidité (affectant la qualité du produit)

10.5 Substances incompatibles

Acides, agents oxydants.

10.6 Produits de décomposition dangereux

Oxydes de carbone, oxydes de potassium.

Section 11 : Information toxicologique

11.1 Informations sur les effets toxiques

Composants		
Chlorure d'ammonium (20 % À 30 %)	12125-02-9	**Toxicité aiguë :** Ingestion/Oral-Rat LD50 • 1650 mg/kg ; **Irritation :** Œil-Lapin • 100 mg • Irritation sévère
Carbonate de potassium (1 % À 5 %)	584-08-7	**Toxicité aiguë :** Ingestion/Oral-Rat LD50 • 1870 mg/kg ; **Toxicité chronique :** Inhalation-Rat TCLo • 43 mg/m³ 17 semaine(s) ; *Cardiaque* : **Altérations de l'ECG ne constituant pas un diagnostic de ce qui précède** ; *Rein, uretère et vessie* : **Autres changements dans la composition de l'urine** ; *Nutrition et métabolisme : Changements chimiques ou de température* : **K** ; **Mutagène :** Synthèse DNA non programmée • Ingestion/voie orale-Rat • 504 g/kg 4 semaine(s)-Continu

Propriétés SGH	Classification
Toxicité aiguë	**EU/CLP**•Manque de données **SGH ONU 3**•Toxicité aiguë - voie orale 5 - ETAmix (voie orale) = 4795 mg/kg **OSHA HCS 2012**•Manque de données
Corrosion/irritation cutanée	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Lésion/irritation grave des yeux	**EU/CLP**•Irritation oculaire 2 **SGH ONU 3**•Irritation oculaire 2 **OSHA HCS 2012**•Irritation oculaire 2
Sensibilisation cutanée	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Sensibilisation respiratoire	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Danger d'aspiration	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Cancérogénicité	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Mutagénicité de cellule germinale	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
Toxicité pour la reproduction	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-SE	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données
STOT-RE	**EU/CLP**•Manque de données **SGH ONU 3**•Manque de données **OSHA HCS 2012**•Manque de données

Effets éventuels sur la santé

Inhalation

Aigu (immédiat)	Aucune donnée disponible
Chronique (différé)	Aucune donnée disponible
Peau	
Aigu (immédiat)	Aucune donnée disponible
Chronique (différé)	Aucune donnée disponible
Yeux	
Aigu (immédiat)	Provoque une irritation oculaire grave.
Chronique (différé)	Aucune donnée disponible
Ingestion	
Aigu (immédiat)	Peut être nocif en cas d'ingestion.
Chronique (différé)	Aucune donnée disponible

Clef aux abréviations
LD = Dose léthale
TC = Concentration toxique

Section 12 : Information écologique

12.1 Toxicité

	CAS	
Kit de prélèvement d'échantillon d'urine Xpert, Kit de prélèvement d'échantillon d'urine Xpert CT/NG	ADD	**Toxicité aquatique-Poisson :** 4 jour(s) LC50 *Capucette* 0,14 mg/L Commentaires : Chlorure d'ammonium (12125-02-9) 30 jour(s) NOEC *Barbue de rivière* 0,006 mg/L Commentaires : Chlorure d'ammonium (12125-02-9) **Toxicité aquatique-Crustacés :** 2 jour(s) EC50 *Ostracode* 0,075-0,126 mg/L Commentaires : Chlorure d'ammonium (12125-02-9) 21 jour(s) NOEC *Puce d'eau* 0,05 mg/L Commentaires : Chlorure d'ammonium (12125-02-9) **Toxicité aquatique-algues et autres plantes aquatiques :** 3 jour(s) EC50 *Algue Hormosira banksii* 0,04-0,1 mg/L Commentaires : Chlorure d'ammonium (12125-02-9)

Toxique pour la vie aquatique. Toxique pour la vie aquatique avec des effets durables.

12.2 Persistance et dégradabilité

Manque de données matérielles.

12.3 Potentiel bioaccumulatif

Manque de données matérielles.

12.4 Mobilité dans le sol

Manque de données matérielles.

12.5 Résultats des évaluations PBT et vPvB

Aucune évaluation PBT ou vPvB n'a été réalisée.

12.6 Autres effets nocifs

Aucune étude n'a été trouvée.

Section 13 : Considérations de mise au rebut

13.1 Méthodes de traitement des déchets

Déchets du produit Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

Conditionnement des déchets Éliminer le contenu et/ou le conteneur conformément aux réglementations locales, régionales, nationales, et/ou internationales.

13.2 Autres informations

Les échantillons biologiques, y compris les cartouches utilisées, doivent être traités comme s'ils étaient susceptibles de transmettre des agents infectieux. Consulter le personnel chargé des déchets environnementaux auprès de l'établissement pour les consignes concernant l'élimination correcte des cartouches usagées et des réactifs inutilisés. Ce produit peut présenter les caractéristiques des déchets dangereux couverts par la loi fédérale américaine de l'EPA sur la conservation et la remise en état des ressources (Resource Conservation and Recovery Act, RCRA) contenant des exigences d'élimination spécifiques. Consulter les réglementations locales et régionales car elles peuvent différer des réglementations nationales. Les établissements en dehors des États-Unis doivent vérifier les exigences de leur pays en matière d'élimination des déchets dangereux.

Section 14 : Informations de transport

	14.1 Numéro ONU	14.2 Nom d'expédition des Nations Unies	14.3 Classe(s) de danger pour le transport	14.4 Groupe d'emballage	14.5 Dangers pour l'environnement
DOT	Sans objet	Non régulé	Sans objet	Sans objet	ADD
TDG	UN3082	SUBSTANCE DANGEREUSE POUR L'ENVIRONNEMENT, LIQUIDE, N.S.A. (Chlorure d'ammonium)	9	III	ADD
IMO/IMDG	UN3082	SUBSTANCE DANGEREUSE POUR L'ENVIRONNEMENT, LIQUIDE, N.S.A. (Chlorure d'ammonium)	9	III	ADD
IATA/ICAO	UN3082	SUBSTANCE DANGEREUSE POUR L'ENVIRONNEMENT, LIQUIDE, N.S.A. (Chlorure d'ammonium)	9	III	ADD

14.6 Précautions spéciales pour l'utilisateur

Rien de précisé.

14.7 Transport en vrac conformément à l'annexe II de la convention MARPOL 73/78 et au recueil IBC

Manque de données.

Section 15 : Informations réglementaires

15.1 Réglementation relative à la sécurité, la santé et l'environnement/législation spécifique à la substance ou au mélange

Classifications de dangers SARA Aiguë

Inventaire						
Composant	**CAS**	**LIS du Canada**	**LES du Canada**	**UE EINECS**	**UE ELNICS**	**TSCA**
Chlorure d'ammonium	12125-02-9	Oui	Non	Oui	Non	Oui
Carbonate de potassium	584-08-7	Oui	Non	Oui	Non	Oui

Fiche signalétique

Date d'entrée en vigueur : Février 2020
Remplace la date : Juillet 2016

Kit de prélèvement d'échantillon d'urine Xpert
Kit de prélèvement d'échantillon urinaire Xpert CT/NG

Canada

Travail

Canada - SIMDUT - Classifications des substances

•Carbonate de potassium	584-08-7	D2B, E
•Chlorure d'ammonium	12125-02-9	D2B

Canada - SIMDUT - Liste de divulgation des ingrédients

•Carbonate de potassium	584-08-7	1 %
•Chlorure d'ammonium	12125-02-9	1 %

Environnement

Canada - LCPE - Liste des substances prioritaires

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

États-Unis

Travail

É.-U. - OSHA - Gestion de la sécurité des procédés - Produits chimiques très dangereux

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

É.-U. - OSHA - Produits chimiques spécifiquement réglementés

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

Environnement

É.-U. - CAA (Clean Air Act) - 1990 Polluants atmosphériques dangereux

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

É.-U. - CERCLA/SARA - Substances dangereuses et leurs quantités à déclarer

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	5 000 lb final RQ ; 2270 kg final RQ

É.-U. - CERCLA/SARA - Radionucléides et leurs quantités à déclarer

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses QR EPCRA

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

É.-U. - CERCLA/SARA - Section 302 Substances extrêmement dangereuses TPQ

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Rapports sur les émissions

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

É.-U. - CERCLA/SARA - Section 313 - Liste des produits chimiques PBT

•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

États-Unis - Californie

Environnement

É.-U. - Californie - Proposition 65 - Liste des substances cancérigènes		
•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour le développement		
•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré
É.-U. - Californie - Proposition 65 - Doses maximales admissibles (MADL)		
•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré
É.-U. - Californie - Proposition 65 - Niveaux de risque non significatifs (NSRL)		
•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Femme		
•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré
É.-U. - Californie - Proposition 65 - Toxicité pour la reproduction - Homme		
•Carbonate de potassium	584-08-7	Non énuméré
•Chlorure d'ammonium	12125-02-9	Non énuméré

15.2 Évaluation de sécurité chimique

Aucune évaluation de sécurité chimique n'a été effectuée.

Section 16 : Autres informations

Phrases pertinentes (code et texte entier)

H302 - Nocif en cas d'ingestion

Déclaration de non-responsabilité

Les informations ci-dessus reposent sur les données dont nous disposons et que nous jugeons correctes. Dans la mesure où ces informations peuvent être utilisées dans des conditions hors de notre contrôle et que nous ne connaissons pas nécessairement, nous n'assumons aucune responsabilité pour les conséquences de leur utilisation et toutes les personnes recevant le produit doivent en déterminer personnellement les effets, les propriétés, ainsi que les mesures de protection et d'élimination nécessaires en rapport avec leurs conditions d'utilisation particulières. Aucune représentation, garantie ou assurance, explicite ou implicite (y compris une garantie d'aptitude ou de qualité marchande pour un but particulier) n'est faite concernant les produits, l'exactitude des informations, les résultats découlant de leur utilisation ou les risques liés à l'utilisation du produit. Il y a lieu de faire preuve de prudence lors de la manipulation et de l'utilisation du produit. Les informations ci-dessus sont fournies en toute bonne foi et avec la conviction qu'elles sont exactes. À la date de publication, nous fournissons toutes les informations pertinentes pour la manipulation prévisible du produit. Cependant, dans l'éventualité d'un incident associé à l'utilisation de ce produit, cette fiche de données de sécurité ne peut pas (et n'est pas conçue pour) se substituer à l'avis d'un personnel correctement formé. Fournir la déclaration de non-responsabilité.

Clef aux abréviations
ADD = Pas de données disponibles

Sicherheitsdatenblatt
Datum des Inkrafttretens: Februar 2020
Ersetzt (Datum): Juli 2016

Xpert Urine Specimen Collection Kit
Xpert CT/NG Urine Specimen Collection Kit

Abschnitt 1: Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

1.1 Produktidentifikator

Produktname	**Xpert Urine Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit**
Produktcode	CT/NGURINE-50; URINE/A-50

1.2 Relevante identifizierte Verwendungen der Substanz oder Mischung und Verwendungen, von denen abgeraten wird

Relevante identifizierte Verwendung(en)	Laborgebrauch

1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Hersteller		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Vereinigte Staaten www.cepheid.com USA: techsupport@cepheid.com
	Telefon (Zentrale)	1 (888) 838-3222 - USA, Option 2
	Telefon (Zentrale)	1 (408) 541-4191 - außerhalb der USA
Lieferant		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Schweden www.cepheidinternational.com EU: support@cepheideurope.com
	Telefon (Zentrale)	+33 563 825 319

1.4 Notrufnummer

Hersteller	+ 1 (800) 535-5053 - INFOTRAC - 24-Stunden-Notruf
Hersteller	+ 1 (352) 323-3500- außerhalb der USA

Abschnitt 2: Mögliche Gefahren

EU/EWG
Nach: Verordnung (EG) Nr. 1272/2008 (CLP)/REACH 1907/2006 [geändert durch 453/2010]

2.1 Einstufung des Stoffs oder Gemischs

CLP	Das folgende SDB gilt für das Fertigprodukt nur, wenn es im Labor benutzt wird. Es enthält flüssige Komponenten, von denen einige als gefriergetrocknetes Pulver und in Form von Reagenzien vorliegen, die in der Kartusche und in einer Nalgenflasche vorhanden sind. Alle Reagenzien sind klare, farblose Flüssigkeiten. Ausnahmen für die Offenlegung einiger Komponentendaten gelten gemäß CLP Artikel 1(5)(d) und 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2). Augenreizung 2 - H319

2.2 Kennzeichnungselemente

CLP

WARNHINWEIS

Gefahrenhinweise H319 - Verursacht schwere Augenreizung

Sicherheitshinweise

Vorbeugung P264 - Nach Gebrauch gründlich waschen.
P280 - Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

Reaktion P305+P351+P338 - BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.
P337+P313 - Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

2.3 Sonstige Gefahren

CLP Nach Verordnung (EG) Nr. 1272/2008 (CLP) gilt dieses Material als gefährlich.

UN GHS Revision 3

Nach: Global harmonisiertes System der Einstufung und Kennzeichnung von Chemikalien (GHS) der UN: Dritte überarbeitete Auflage

2.1 Einstufung des Stoffs oder Gemischs

UN GHS Akute Toxizität, oral 5
Augenreizung 2
Gefährlich für Wasserorganismen Akut 1
Gefährlich für Wasserorganismen Chronisch 1

2.2 Kennzeichnungselemente

UN GHS

WARNHINWEIS

Gefahrenhinweise Möglicherweise gesundheitsschädlich bei Verschlucken
Verursacht schwere Augenreizung
Sehr giftig für Wasserorganismen
Sehr giftig für Wasserorganismen mit langfristiger Wirkung

Sicherheitshinweise

Vorbeugung Nach Gebrauch gründlich waschen.
Freisetzung in die Umwelt vermeiden.
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

Reaktion	BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen. Verschüttete Mengen aufnehmen.
Lagerung/Entsorgung	Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

2.3 Sonstige Gefahren

UN GHS	Nach dem global harmonisierten System zur Einstufung und Kennzeichnung (GHS) gilt dieses Produkt als gefährlich.

Vereinigte Staaten (VS)
Nach: OSHA 29 CFR 1910.1200 HCS

2.1 Einstufung des Stoffs oder Gemischs

OSHA HCS 2012	Augenreizung 2

2.2 Kennzeichnungselemente

OSHA HCS 2012

WARNHINWEIS

Gefahrenhinweise	Verursacht schwere Augenreizung
Sicherheitshinweise	
Vorbeugung	Nach Gebrauch gründlich waschen. Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.
Reaktion	BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

2.3 Sonstige Gefahren

OSHA HCS 2012	Nach den Vorschriften der USA (29 CFR 1910.1200 - Norm für Gefahrenkommunikation) gilt dieses Produkt als gefährlich.

Kanada
Nach: WHMIS

2.1 Einstufung des Stoffs oder Gemischs

WHMIS	Sonstige Giftwirkungen - D2B

2.2 Kennzeichnungselemente

WHMIS

Sonstige Giftwirkungen - D2B

2.3 Sonstige Gefahren

WHMIS In Kanada ist das oben genannte Produkt nach dem Workplace Hazardous Materials Information System (WHMIS) als gefährlich eingestuft.

2.4 Sonstige Angaben

Alle anderen Reagenzien, Körner und andere Bestandteile sind in Konzentrationen unter 1 % im Gemisch vorhanden oder gelten nicht als gefährlich gemäß den US-Richtlinien für die Gefahrenkommunikation (29 CFR 1910.1200), den EU-Richtlinien für die Einstufung und Etikettierung von Substanzen oder Gemischen oder dem globalen Harmonisierungssystem für die Einstufung und Etikettierung von Substanzen oder Gemischen.

Abschnitt 3: Zusammensetzung/Angaben zu den Bestandteilen

3.1 Stoffe

Material erfüllt nicht die Kriterien einer Substanz.

3.2 Gemische

Zusammensetzung					
Chemische Bezeichnung	**Kennzeichnung**	**%**	**LD50/LC50**	**Klassifizierungen nach der Verordnung/Richtlinie**	**Bemerkungen**
Ammoniumchlorid	**CAS:** 12125-02-9 **EG-Nummer:** 235-186-4 **EU-Index:** 017-014-00-8	20 % BIS 30 %	Verschlucken/oral-Ratte LD50 • 1650 mg/kg	**EU CLP:** Anhang VI, Tabelle 3.1: Akute Tox. 4 *, H302; Augenreizung 2, H319 **UN GHS Revision 3:** Akute Tox. 4 (Verschlucken); Augenreizung 2; Aquatisch Akut 1; Aquatisch Chronisch 1 **OSHA HCS 2012:** Akute Tox. 4 (Verschlucken); Augenreizung 2	KDV
Kaliumcarbonat	**CAS:**584-08-7 **EG-Nummer:** 209-529-3	1 % BIS 5 %	Verschlucken/oral-Ratte LD50 • 1870 mg/kg	**EU CLP:** Akute Tox. 4, H302 **UN GHS Revision 3:** Akute Tox. 4 (Verschlucken); Augenreizung 2B **OSHA HCS 2012:** Akute Tox. 4 (Verschlucken); Augenreizung 2B	KDV

Vollständiger Text der H-Hinweise siehe Abschnitt 16.

Abschnitt 4: Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

Einatmen Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Verunfallten an die frische Luft bringen. Bei Atemschwierigkeiten Sauerstoffzufuhr einleiten. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat; künstliche Beatmung mit einer mit Einwegventil ausgestatteten Taschen-Sauerstoffmaske oder sonstigem geeigneten medizinischen Beatmungsgerät einleiten. Bei Atemstillstand künstliche Beatmung umgehend einleiten.

Haut Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei geringem Hautkontakt Material nicht auf andere Hautbereiche verteilen. Im Falle eines Hautkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Verunreinigte Kleidung entfernen und isolieren.

Augen	Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Im Falle eines Augenkontakts mit dem Stoff unter fließendem Wasser sofort für mindestens 20 Minuten abwaschen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
Verschlucken	Es ist keine erste Hilfe erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird. Bei Einnahme Mund mit Wasser ausspülen (nur, wenn die Person bei Bewusstsein ist). KEIN Erbrechen herbeiführen. Keine Mund-zu-Mund-Wiederbelebung versuchen, wenn der/die Verunfallte die Substanz verschluckt hat. Bei Einnahme sofort Arzt zu Rate ziehen.

4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen

Siehe Abschnitt 11 - Toxikologische Angaben.

4.3 Hinweis auf ärztliche Soforthilfe oder Spezialbehandlung

Hinweise für den Arzt	Alle Behandlungsmaßnahmen sollten auf den beobachteten Anzeichen und Symptomen von Erschöpfung beim Patienten basieren. Außerdem ist zu berücksichtigen, dass es möglicherweise zum Kontakt mit anderen Materialien zusätzlich zu diesem Produkt kam.

Abschnitt 5: Maßnahmen zur Brandbekämpfung

5.1 Löschmittel

Geeignete Löschmittel	GROSSBRAND: Trockenlöschmittel, CO2, alkoholresistenter Schaum oder Wasserstrahl. KLEINBRAND: Trockenlöschmittel, CO2 oder Wasserstrahl.
Ungeeignete Löschmittel	Keine Daten verfügbar

5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren

Ungewöhnliche Brand-und Explosionsgefahren	Kann zur Bildung giftiger Kohlenoxid- und Stickstoffoxiddämpfe führen.
Gefährliche Verbrennungsprodukte	Keine Daten verfügbar

5.3 Hinweise für die Brandbekämpfung

Für die Feuerbekämpfung vorgesehene Standardarbeitsschutzbekleidung bietet einen begrenzten Schutz NUR in Brandfällen; sie ist ineffektiv bei Verschüttungen, wo ein direkter Kontakt mit dem Stoff möglich ist.
Chemikalienschutzbekleidung tragen, die speziell vom Hersteller empfohlen wird. Sie kann wenig oder keinen Thermoschutz bieten.
Umgebungsluftunabhängiges Atemschutzgerät (SCBA) für Überdruckbetrieb tragen.
KLEINBRAND: Behälter aus der Brandzone entfernen, wenn es kein Risiko darstellt.

Abschnitt 6: Maßnahmen bei unbeabsichtigter Freisetzung

6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Persönliche Schutzmaßnahmen Wenn eine Kartusche bricht, dann sind diese persönlichen Vorkehrungen anzuwenden. Entsprechende Schutzkleidung tragen. Nicht durch das verschüttete Material hindurch gehen. Beschädigte Behälter oder verschüttetes Material ohne geeignete Schutzkleidung nicht anfassen. Geschlossene Räume be- oder entlüften.

Sofortmaßnahmen Es sind keine Notfallmaßnahmen erforderlich, sofern der Stoff unter normalen Bedingungen und nach den Empfehlungen benutzt wird.

6.2 Umweltschutzmaßnahmen

Nicht in Gewässer, die Kanalisation, Keller oder enge Räume gelangen lassen.

6.3 Methoden und Material für Rückhaltung und Reinigung

Einkapselung/Aufräumarbeiten Bei kleinen Verschüttungen Handschuhe tragen und Verschüttung mit einem Papiertuch aufnehmen. Verschüttetes Material nicht durch den Abfluss entsorgen.

6.4 Verweis auf andere Abschnitte

Siehe Abschnitt 8 - Einwirkungskontrolle/Personenschutz und Abschnitt 13 - Überlegungen zur Entsorgung.

Abschnitt 7: Handhabung und Lagerung

7.1 Schutzmaßnahmen zur sicheren Handhabung

Handhabung Keine spezielle Handhabung notwendig. Wenn eine Kartusche gebrochen ist, dann ist der Kontakt mit verschütteten Reagenzien zu vermeiden. Kontakt mit Haut und Augen vermeiden.

7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Umweltverträglichkeiten

Lagerung Produkt gemäß der Etikettierung lagern. Behälter/Verpackung dicht verschlossen an kühlem, gut belüftetem Ort lagern. Von nicht kompatiblem Material fernhalten.

7.3 Spezifische Endanwendungen

Siehe Abschnitt 1.2 - Relevante identifizierte Nutzung.

Abschnitt 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstung

8.1 Zu überwachende Parameter

Expositionsgrenzwerte/Richtlinien			
	Ergebnis	**ACGIH**	**NIOSH**
Ammoniumchlorid (12125-02-9)	STELs	20 mg/m3 STEL (Dampf)	20 mg/m3 STEL (Dampf)
	zeitlich gewichtete Durchschnitte	10 mg/m3 TWA (Dampf)	10 mg/m3 TWA (Dampf)

8.2 Begrenzung und Überwachung der Exposition

Technische Maßnahmen/Kontrollen	Es ist eine gute allgemeine Belüftung anzuwenden. Die Belüftungszahl sollte den Bedingungen entsprechen. Prozesskammern, lokale Abzugsanlage oder andere technische Kontrollmittel verwenden, um die Konzentration in der Luft unter den empfohlenen Grenzwerten zu halten. Wenn keine Grenzwerte festgelegt wurden, sind die Konzentrationen auf einem akzeptablen Niveau zu halten.
Persönliche Schutzausrüstung	
Atemwege	OSHA-Vorgaben für Atemschutzgeräte aus 29 CFR 1910.134 oder der Europäischen Norm EN 149 befolgen. Nach NIOSH/MSHA oder der europäischen Norm EN 149 zugelassenes Atemschutzgerät benutzen, wenn die Grenzwerte überschritten werden oder Symptome auftreten.
Augen/Gesicht	Schutzbrillen gegen Chemikalienspritzer tragen.
Haut/Körper	In einer Laborumgebung sind mindestens Handschuhe und ein Laborkittel zu tragen, um den Hautkontakt zu minimieren.
Umweltkontrollmaßnahmen	Beste Praktiken bei Bauleitung und Abfallentsorgung anwenden.

Schlüssel für Abkürzungen
ACGIH = American Conference of Governmental Industrial Hygiene
NIOSH = National Institute of Occupational Safety and Health
OSHA = Agentur für Sicherheit und Gesundheitsschutz am Arbeitsplatz
Kurzzeitgrenzwerte (STEL-Werte) basieren auf einer 15-minütigen Exposition
TWA = Zeitlich gewichtete Mittelwerte basieren auf einer Exposition von 8 Stunden/Tag, 40 Stunden/Woche

Abschnitt 9: Physikalische und chemische Eigenschaften

9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften

Materialbeschreibung			
Physische Gestalt	Flüssigkeit	Aussehen/Beschreibung	Die Reagenzien sind klare, farb- und geruchlose Flüssigkeiten, die in wässrigen Lösungen primär gepuffert sind.
Farbe	Klar	Geruch	Geruchlos
Geruchsschwelle	Fehlende Daten		
Allgemeine Eigenschaften			
Siedepunkt	100 °C (212 °F)	Schmelzpunkt/Gefrierpunkt	0 °C (32 °F)
Zersetzungstemperatur	Fehlende Daten	pH	8 bis 8,3 (Feststoffe und andere flüssige Reagenzien)
Spezifisches Gewicht/Relative Dichte	Fehlende Daten	Wasserlöslichkeit	Fehlende Daten
Viskosität	Fehlende Daten	Explosive Eigenschaften	Fehlende Daten
Oxidationseigenschaften:	Fehlende Daten		
Volatilität			
Dampfdruck	Fehlende Daten	Dampfdichte	Fehlende Daten
Verdunstungsrate	Fehlende Daten		
Entflammbarkeit			
Flammpunkt	Fehlende Daten	Obere Expositionsgrenze	Fehlende Daten
Untere Expositionsgrenze	Fehlende Daten	Selbstzündung	Fehlende Daten
Entflammbarkeit (Feststoff, Gas)	Fehlende Daten		
Umwelt			
Oktanol/Wasser-Verteilungskoeffizient	Fehlende Daten		

9.2 Sonstige Angaben

Keine zusätzlichen physikalischen und chemischen Parameter vermerkt.

Abschnitt 10: Stabilität und Reaktivität

10.1 Reaktivität

Keine gefährliche Reaktion bekannt unter Bedingungen der normalen Verwendung.

10.2 Chemische Stabilität

Stabil

10.3 Möglichkeit gefährlicher Reaktionen

Eine gefährliche Polymerisierung findet nicht statt.

10.4 Zu vermeidende Bedingungen

Wärme, Feuchtigkeit (mit Auswirkung auf die Produktqualität)

10.5 Inkompatible Materialien

Säuren, Oxidationsmittel.

10.6 Gefährliche Zersetzungsprodukte

Kohlenoxide, Kaliumoxide.

Abschnitt 11: Toxikologische Angaben

11.1 Angaben zu toxikologischen Wirkungen

Bestandteile		
Ammoniumchlorid (20 % BIS 30 %)	12125-02-9	**Akute Toxizität:** Verschlucken/oral-Ratte LD50 • 1650 mg/kg; **Reizung:** Auge-Kaninchen • 100 mg • Schwere Reizung
Kaliumcarbonat (1 % BIS 5 %)	584-08-7	**Akute Toxizität:** Verschlucken/oral-Ratte LD50 • 1870 mg/kg; **Multidosis-Toxizität:** Einatmen-Ratte TCLo • 43 mg/m³ 17 Woche(n); *Herz*:**EKG-Veränderungen anders als die obigen Diagnosen**; *Niere, Harnleiter, Blase*:**Andere Veränderungen der Urinzusammensetzung**; *Ernährung und Bruttostoffwechsel:Änderungen in der Chemie oder Temperatur*: **K**; **Mutagen:** Unplanmäßige DNA-Synthese • Verschlucken/oral-Ratte • 504 g/kg 4 Woche(n)-ständig

GHS-Eigenschaften	**Klassifizierung**
Akute Toxizität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Akute Toxizität - Oral 5 - ATEmix (oral) = 4795 mg/kg **OSHA HCS 2012**•Fehlende Daten
Hautätzende Wirkung/Reizung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Schwere Augenschäden/Augenreizung	**EU/CLP**•Augenreizung 2 **UN GHS 3**•Augenreizung 2 **OSHA HCS 2012**•Augenreizung 2
Hautsensibilisierung	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

GHS-Eigenschaften	Klassifizierung
Sensibilisierung der Atemwege	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Aspirationsgefahr	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Karzinogenität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Keimzell-Mutagenität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
Reproduktionstoxizität	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-SE	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten
STOT-RE	**EU/CLP**•Fehlende Daten **UN GHS 3**•Fehlende Daten **OSHA HCS 2012**•Fehlende Daten

Mögliche gesundheitliche Auswirkungen

Einatmen
Akut (sofort) Keine Daten verfügbar
Chronisch (verzögert) Keine Daten verfügbar

Haut
Akut (sofort) Keine Daten verfügbar
Chronisch (verzögert) Keine Daten verfügbar

Augen
Akut (sofort) Verursacht schwere Augenreizungen.
Chronisch (verzögert) Keine Daten verfügbar

Verschlucken
Akut (sofort) Kann bei Verschlucken schädlich sein.
Chronisch (verzögert) Keine Daten verfügbar

Schlüssel für Abkürzungen
LD = Letale Dosis
TC = Toxische Konzentration

Abschnitt 12: Umweltbezogene Angaben

12.1 Toxizität

	CAS	
Xpert Urine Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit	KDV	**Aquatische Toxizität-Fische:** 4 Tag(e) LC50 *Atlantik-Ährenfisch* 0,14 mg/l Kommentare: Ammoniumchlorid (12125-02-9) 30 Tag(e) NOEC *Katzenwels* 0,006 mg/l Kommentare: Ammoniumchlorid (12125-02-9) **Aquatische Toxizität-Krebstiere:** 2 Tag(e) EC50 *Ostrakoden* 0,075-0,126 mg/l Kommentare: Ammoniumchlorid (12125-02-9) 21 Tag(e) NOEC *Wasserfloh* 0,05 mg/l Kommentare: Ammoniumchlorid (12125-02-9) **Aquatische Toxizität-Algen und andere Wasserpflanzen:** 3 Tag(e) EC50 *Hormosira banksii* 0,04-0,1 mg/l Kommentare: Ammoniumchlorid (12125-02-9)

Giftig für Wasserorganismen. Giftig für Wasserorganismen, mit langfristiger Wirkung.

12.2 Persistenz und Abbaubarkeit

Materialdaten fehlen.

12.3 Bioakkumulationspotenzial

Materialdaten fehlen.

12.4 Mobilität im Boden

Materialdaten fehlen.

12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Es wurde keine PBT- oder vPvB-Bewertung durchgeführt.

12.6 Andere schädliche Wirkungen

Es wurden keine Studien gefunden.

Abschnitt 13: Hinweise zur Entsorgung

13.1 Verfahren der Abfallbehandlung

Produktabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

Verpackungsabfall Entsorgen von Inhalten und/oder Behälter in Übereinstimmung mit den örtlichen, regionalen, nationalen und/oder internationalen Vorschriften.

13.2 Sonstige Angaben

Bei biologischen Proben, einschließlich gebrauchter Kartuschen, ist davon auszugehen, dass sie Infektionserreger übertragen, und sie sind entsprechend zu behandeln. Konsultieren Sie das Personal für umweltgerechte Abfallentsorgung in Ihrer Institution für die ordnungsgemäße Entsorgung gebrauchter Kartuschen und unbenutzter Reagenzien. Dieser Stoff kann Eigenschaften von Sondermüll gemäß des in den USA geltenden EPA Resource Conservation and Recovery Act (RCRA) aufweisen und die Erfüllung spezieller Entsorgungsvorgaben erfordern. Prüfen Sie die bundesstaatlichen und lokalen Vorschriften daraufhin, wie sie sich von den bundesstaatlichen Entsorgungsvorschriften unterscheiden. Institutionen außerhalb der USA sollten die in ihrem Land geltenden Entsorgungsvorgaben für Sondermüll prüfen.

Abschnitt 14: Angaben zum Transport

	14.1 UN-Nummer	14.2 Korrekte UN-Bezeichnung des Frachtgutes	14.3 Transportgefahrenklasse(n)	14.4 Verpackungsgruppe	14.5 Umweltrisiken
DOT	Nicht zutreffend	Nicht reglementiert	Nicht zutreffend	Nicht zutreffend	KDV
TDG	UN3082	UMWELTGEFÄHRLICHE SUBSTANZ, FLÜSSIGKEIT, NICHT NÄHER BEZEICHNET (Ammoniumchlorid)	9	III	KDV
IMO/IMDG	UN3082	UMWELTGEFÄHRLICHE SUBSTANZ, FLÜSSIGKEIT, NICHT NÄHER BEZEICHNET (Ammoniumchlorid)	9	III	KDV
IATA/ICAO	UN3082	UMWELTGEFÄHRLICHE SUBSTANZ, FLÜSSIGKEIT, NICHT NÄHER BEZEICHNET (Ammoniumchlorid)	9	III	KDV

14.6 Besondere Vorsichtsmaßnahmen für den Verwender

Keine Angaben.

14.7 Massengutbeförderung gemäß Anhang II des MARPOL-Übereinkommens 73/78 und gemäß IBC-Code

Fehlende Daten.

Abschnitt 15: Rechtsvorschriften

15.1 Vorschriften zur Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

SARA - Klassifizierung Akutvon Gefahren

Inventar						
Bestandteil	**CAS**	**Kanada DSL**	**Kanada NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Ammoniumchlorid	12125-02-9	Ja	Nein	Ja	Nein	Ja
Kaliumcarbonat	584-08-7	Ja	Nein	Ja	Nein	Ja

Kanada

Arbeit

Kanada - WHMIS - Klassifizierung von Substanzen

•Kaliumcarbonat	584-08-7	D2B, E
•Ammoniumchlorid	12125-02-9	D2B

Kanada - WHMIS - Kanadische Offenbarungsliste der Inhaltsstoffe (IDL)

•Kaliumcarbonat	584-08-7	1 %
•Ammoniumchlorid	12125-02-9	1 %

Umwelt

Kanada - CEPA - Liste prioritärer Stoffe

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

Vereinigte Staaten

Arbeit

USA - OSHA - Prozesssicherheitsmanagement - Hochgefährliche Chemikalien

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

USA - OSHA - Speziell regulierte Chemikalien

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

Umwelt

USA - CAA (Clean Air Act) - 1990 Gefährliche Schadstoffe in der Luft

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

USA - CERCLA/SARA - Gefährliche Stoffe und deren meldepflichtige Mengen

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	5000 lb endgültige RQ; 2270 kg endgültige RQ

USA - CERCLA/SARA - Radionuklide und ihre berichtspflichtigen Mengen

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302 - Äußerst gefährliche Stoffe EPCRA RQ-Werte

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 302 - Äußerst gefährliche Stoffe TPQ-Werte

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 - Emissionsmeldung

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

USA - CERCLA/SARA - Abschnitt 313 - Verzeichnis von PBT-Chemikalien

•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

Vereinigte Staaten - Kalifornien

Umwelt

USA - Kalifornien - Proposition 65 - Liste der krebserzeugenden Stoffe		
•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet
USA - Kalifornien - Proposition 65 - Entwicklungstoxizität		
•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet
USA - Kalifornien - Proposition 65 - Maximal zulässige Dosierungen (MADL)		
•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet
USA - Kalifornien - Proposition 65 - Ohne Nennenswerte Risiken (NSRL)		
•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet
USA - Kalifornien - Proposition 65 - Weibliche Reproduktionstoxizität		
•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet
USA - Kalifornien - Proposition 65 - Männliche Reproduktionstoxizität		
•Kaliumcarbonat	584-08-7	Nicht gelistet
•Ammoniumchlorid	12125-02-9	Nicht gelistet

15.2 Stoffsicherheitsbeurteilung

Es wurde keine chemische Sicherheitsanalyse durchgeführt.

Abschnitt 16: Sonstige Angaben

Relevante Sätze (Code & Volltext)

H302 - Gesundheitsschädlich bei Verschlucken

Haftungsausschluss/ Haftungshinweis

Die obigen Informationen basieren auf Daten, die uns verfügbar sind und die wir für korrekt halten. Da die Informationen unter Bedingungen angewendet werden können, die außerhalb unserer Kontrolle liegen und mit denen wir möglicherweise nicht vertraut sind, übernehmen wir keine Verantwortung für die Ergebnisse der Nutzung und alle Personen, die sie erhalten, müssen ihre eigenen Festlegungen bezüglich der Wirkungen, Eigenschaften, Schutzmaßnahmen und Entsorgung vornehmen, die zu den jeweiligen Bedingungen gehören. Es wird keine Zusicherung, Gewährleistung oder Garantie, weder in ausdrücklicher noch in implizierter Form (einschließlich einer Garantie für die Eignung oder Handelsüblichkeit), erteilt werden im Hinblick auf die Stoffe, die Genauigkeit dieser Informationen, die Ergebnisse, die aus deren Nutzung resultieren, oder die Gefahren, die mit der Nutzung des Stoffes verbunden sind. Bei der Handhabung und Nutzung des Stoffs ist Vorsicht anzuwenden. Die obigen Informationen wurden nach bestem Wissen angegeben und für akkurat gehalten. Zum Datum der Ausstellung bieten wir alle Informationen, die für die zu erwartende Handhabung des Stoffs relevant sind. Bei einem Vorfall mit diesem Produkt stellt dieses Sicherheitsdatenblatt keinen Ersatz für die Rücksprache mit entsprechend geschultem Personal dar und ist nicht dazu gedacht. Bitte Haftungsausschluss einfügen.

Schlüssel für Abkürzungen
KDV = Keine Daten verfügbar

Scheda dati di sicurezza
Data di decorrenza: Febbraio 2020
Sostituisce la versione del: Luglio 2016

Kit di prelievo dei campioni di urina Xpert
Kit di prelievo dei campioni di urina Xpert CT/NG

Sezione 1: Identificazione della sostanza/miscela e dell'azienda/impresa

1.1 Identificatore del prodotto

Nome prodotto **Kit di prelievo dei campioni di urina Xpert, Kit di prelievo dei campioni di urina Xpert CT/NG**

Codice prodotto CT/NGURINE-50; URINE/A-50

1.2 Usi pertinenti identificati della sostanza o della miscela e utilizzi sconsigliati

Usi pertinenti identificati Uso in laboratorio

1.3 Dettagli del fornitore della scheda dati di sicurezza

Produttore
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Stati Uniti
www.cepheid.com
USA: techsupport@cepheid.com

Telefono (generale) 1 (888) 838-3222 - USA Opzione 2

Telefono (generale) 1 (408) 541-4191 - Fuori dagli USA

Fornitore
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Svezia
www.cepheidinternational.com
UE: support@cepheideurope.com

Telefono (generale) +33 563 825 319

1.4 Numero telefonico di emergenza

Produttore + 1 (800) 535-5053 - INFOTRAC - Numero telefonico di emergenza attivo 24 ore su 24

Produttore + 1 (352) 323-3500- Fuori dagli USA

Sezione 2: Identificazione dei pericoli

UE/CEE

In ottemperanza a: Normativa (CE) N.1272/2008 (CLP)/REACH 1907/2006 [emendata dalla 453/2010]

2.1 Classificazione della sostanza o della miscela

CLP La seguente Scheda informativa in materia di sicurezza (SDS) è da considerarsi valida per il prodotto finito finale solo se usato in laboratorio. Contiene componenti liquidi, alcuni dei quali sono in polveri liofilizzate e reagenti che sono contenuti nella cartuccia e in una bottiglia Nalgene. Tutti i reagenti sono liquidi trasparenti e incolori. Le esenzioni per la divulgazione di alcune informazioni relative ai componenti sono a norma dell'articolo CLP 1(5)(d) e 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).
Irritazione oculare 2 - H319

2.2 Elementi dell'etichetta

CLP

ATTENZIONE

Frasi di rischio H319 - Provoca grave irritazione oculare.

Frasi di prudenza

Prevenzione P264 - Lavare accuratamente dopo l'uso.
P280 - Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso.

Risposta P305+P351+P338 - IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
P337+P313 - Se l'irritazione degli occhi persiste: consultare un medico.

2.3 Altri rischi

CLP Ai sensi del Regolamento (CE) n. 1272/2008 (CLP), questo materiale è considerato pericoloso.

UN GHS Revisione 3

In ottemperanza a: Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN Globally Harmonized System of Classification and Labeling of Chemicals, GHS):
Revisione della terza edizione

2.1 Classificazione della sostanza o della miscela

UN GHS Tossicità acuta - per via orale 5
Irritazione oculare 2
Pericoloso per l'ambiente acquatico - pericolo acuto 1
Pericoloso per l'ambiente acquatico - pericolo cronico 1

2.2 Elementi dell'etichetta

UN GHS

ATTENZIONE

Frasi di rischio Può essere nocivo se ingerito
Provoca grave irritazione oculare
Molto tossico per l'ambiente acquatico
Molto tossico per l'ambiente acquatico con effetti di lunga durata

Frasi di prudenza

Prevenzione Lavare accuratamente dopo l'uso.
Non disperdere nell'ambiente.
Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso.

Risposta	IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. Se l'irritazione degli occhi persiste: consultare un medico. In caso di malessere, contattare un CENTRO ANTIVELENI o un medico. Raccogliere la fuoriuscita.
Stoccaggio/Smaltimento	Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

2.3 Altri rischi

UN GHS	In conformità al Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche definito dalle Nazioni Unite (UN GHS) questo prodotto è considerato pericoloso.

Stati Uniti (USA)
In ottemperanza a: OSHA 29 CFR 1910.1200 HCS

2.1 Classificazione della sostanza o della miscela

OSHA HCS 2012	Irritazione oculare 2

2.2 Elementi dell'etichetta

OSHA HCS 2012

ATTENZIONE

Frasi di rischio	Provoca grave irritazione oculare.
Frasi di prudenza	
Prevenzione	Lavare accuratamente dopo l'uso. Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso.
Risposta	IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. Se l'irritazione degli occhi persiste: consultare un medico.

2.3 Altri rischi

OSHA HCS 2012	Ai sensi della normativa statunitense (29 CFR 1910.1200 - Standard per la comunicazione dei pericoli), questo prodotto è considerato pericoloso.

Canada
In ottemperanza a: WHMIS

2.1 Classificazione della sostanza o della miscela

WHMIS	Altri effetti tossici - D2B

2.2 Elementi dell'etichetta

WHMIS

Altri effetti tossici - D2B

2.3 Altri rischi

WHMIS

In Canada, il prodotto di cui sopra è considerato pericoloso ai sensi del sistema di informazioni sui materiali pericolosi sul luogo di lavoro (Workplace Hazardous Materials Information System, WHMIS).

2.4 Altre informazioni

Tutti gli altri reagenti, le perline e i costituenti hanno concentrazioni inferiori all'1% nella miscela o non sono considerati pericolosi per le normative sulla comunicazione del pericolo degli USA (29 CFR 1910.1200), le direttive UE per la classificazione e l'etichettatura delle sostanze e delle miscele o per il Sistema di armonizzazione globale della classificazione ed etichettatura delle sostanze chimiche e delle miscele.

Sezione 3: Composizione/Informazioni sugli ingredienti

3.1 Sostanze

Il materiale non soddisfa i criteri di classificazione come sostanza.

3.2 Miscele

Composizione					
Nome Chimico	**Identificatori**	**%**	**DL50/CL50**	**Classificazioni Secondo Regolamento/ Direttiva**	**Commenti**
Cloruro d'ammonio	**CAS:** 12125-02-9 **Numero CE:** 235-186-4 **Indice UE:** 017-014-00-8	DAL 20% AL 30%	Ingestione/Orale-Ratto DL50 • 1650 mg/kg	**UE CLP:** Allegato VI, Tabella 3.1: Toss. acuta 4 *, H302; Irrit. occhi 2, H319 **UN GHS Revisione 3:** Toss. acuta 4 (orale); Irrit. occhi 2; Acquatica acuta 1; Acquatica cronica 1 **OSHA HCS 2012:** Toss. acuta 4 (orale); Irrit. occhi 2	NDD
Carbonato di potassio	**CAS:**584-08-7 **Numero CE:** 209-529-3	DALL'1% AL 5%	Ingestione/Orale-Ratto DL50 • 1870 mg/kg	**UE CLP:** Toss. acuta 4, H302 **UN GHS Revisione 3:** Toss. acuta 4 (orale); Irrit. occhi 2B **OSHA HCS 2012:** Toss. acuta 4 (orale); Irrit. occhi 2B	NDD

Per l'elenco completo delle frasi H, vedere la Sezione 16.

Sezione 4: Misure di pronto soccorso

4.1 Descrizione delle misure di pronto soccorso

Inalazione

Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. Portare la persona colpita all'aria aperta. Somministrare ossigeno se la respirazione è difficile. Non usare il metodo bocca-a-bocca se la vittima ha inalato la sostanza; effettuare la respirazione artificiale con l'ausilio di una mascherina con valvola unidirezionale o altro dispositivo medico adeguato. Se la vittima non respira, effettuare la respirazione artificiale.

Cute	Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di limitato contatto con la pelle, evitare la dispersione del materiale sulla pelle non interessata. In caso di contatto con la sostanza, sciacquare immediatamente la pelle con acqua corrente per almeno 20 minuti. Rimuovere e isolare gli indumenti contaminati.
Occhi	Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di contatto con la sostanza, sciacquare immediatamente gli occhi con acqua corrente per almeno 20 minuti. Se l'irritazione degli occhi persiste: consultare un medico.
Ingestione	Non si prevede la necessità di misure di pronto soccorso se il materiale viene utilizzato in condizioni normali come raccomandato. In caso di ingestione, sciacquare la bocca con acqua (solamente se l'infortunato è cosciente). NON provocare il vomito. Non usare il metodo bocca-a-bocca se la vittima ha ingerito la sostanza. In caso di ingestione consultare immediatamente un medico.

4.2 Sintomi ed effetti più importanti, acuti e ritardati

Consultare la Sezione 11 - Informazioni tossicologiche.

4.3 Indicazione delle attenzioni mediche immediate e dei trattamenti speciali necessari

Note per il medico	Tutte le cure dovrebbero basarsi sull'osservazione di segni e sintomi di malessere nel paziente. Dovrebbe essere presa in considerazione la possibilità di sovraesposizione a materiali diversi da questo prodotto.

Sezione 5: Misure antincendio

5.1 Mezzi di estinzione

Mezzi di estinzione adeguati	INCENDI DI AMPIE DIMENSIONI: composto chimico secco, CO_2, schiumogeno resistente all'alcol o getto d'acqua. INCENDI DI DIMENSIONI RIDOTTE: composto chimico secco, CO_2 o getto d'acqua.
Mezzi di estinzione non adeguati	Nessun dato disponibile

5.2 Rischi speciali che scaturiscono dalla sostanza o dalla miscela

Rischi di esplosione e incendi inconsueti	Può emettere vapori tossici di ossidi di carbonio e ossidi di azoto.
Prodotti di combustione pericolosi	Nessun dato disponibile

5.3 Consiglio per i vigili del fuoco

Gli indumenti antincendio strutturali forniscono una protezione limitata SOLO in condizioni di incendio; non sono efficaci in condizioni di fuoriuscite in cui è probabile il contatto diretto con la sostanza.
Indossare abbigliamento protettivo contro gli agenti chimici specificatamente raccomandato dal produttore. Potrebbe fornire limitata o nessuna protezione termica.
Indossare un apparato di respirazione autonomo funzionante a pressione positiva (self-contained breathing apparatus, SCBA).
INCENDI DI DIMENSIONI RIDOTTE: spostare i contenitori dall'area colpita dall'incendio se non comporta alcun rischio.

Sezione 6: Misure contro il versamento accidentale

6.1 Precauzioni personali, dispositivi di protezione e procedure di emergenza

Precauzioni personali	Nel caso in cui si rompa una cartuccia, è possibile applicare queste precauzioni personali. Usare indumenti protettivi adatti. Non camminare sul materiale versato. Toccare i contenitori danneggiati o il materiale versato solo dopo aver indossato l'abbigliamento protettivo adeguato. Ventilare le aree chiuse.
Procedure di emergenza	Non si prevede la necessità di procedure di emergenza se il materiale viene utilizzato in condizioni normali come raccomandato.

6.2 Precauzioni ambientali

Evitare l'ingresso in corsi d'acqua, fognature, seminterrati o aree confinate.

6.3 Metodi e materiali per il contenimento e la pulizia

Misure di contenimento/pulizia	Per piccole fuoriuscite, indossare guanti e assorbire la fuoriuscita con un tovagliolo di carta. Non gettare il materiale fuoriuscito nei tubi di scarico.

6.4 Riferimento ad altre sezioni

Consultare la Sezione 8 - Controlli dell'esposizione / Protezione personale e la Sezione 13 - Considerazioni per lo smaltimento.

Sezione 7: Manipolazione e stoccaggio

7.1 Precauzioni per la manipolazione sicura

Manipolazione	Non è necessario nessun trattamento speciale. Nel caso in cui si rompa una cartuccia, evitare il contatto con i reagenti fuoriusciti. Evitare il contatto con gli occhi e con la pelle.

7.2 Condizioni per lo stoccaggio sicuro, incompatibilità eventuali incluse

Stoccaggio	Conservare secondo le indicazioni presenti sull'etichetta del prodotto. Conservare il recipiente/contenitore ben chiuso in luogo fresco e ben ventilato. Tenere lontano dai materiali incompatibili.

7.3 Usi finali specifici

Consultare la Sezione 1.2 - Usi pertinenti identificati.

Sezione 8: Controlli di esposizione / Protezione personale

8.1 Parametri di controllo

Limiti di Esposizione / Linee Guida			
	Risultato	**ACGIH**	**NIOSH**
Cloruro d'ammonio (12125-02-9)	STEL	20 mg/m3 STEL (fumo)	20 mg/m3 STEL (fumo)
	TWA	10 mg/m3 TWA (fumo)	10 mg/m3 TWA (fumo)

8.2 Controlli di esposizione

Misure/Controlli tecnici Garantire una ventilazione generale adeguata. I regimi di ventilazione devono essere adeguati alle condizioni. Se applicabile, utilizzare camere di protezione dei processi, impianti di ventilazione locale o altri controlli tecnici per mantenere i livelli di contaminanti aerei al di sotto dei limiti di esposizione raccomandati. Qualora i limiti di esposizione non fossero stati stabiliti, mantenere i contaminanti aerei a un livello accettabile.

Dispositivi di protezione individuale

Respirazione Attenersi alle indicazioni del respiratore OSHA disponibili in 29 CFR 1910.134 o nella norma europea EN 149. In caso di superamento dei limiti di esposizione o manifestazione di sintomi, usare un respiratore approvato da NIOSH/MSHA o dalla norma europea EN 149.

Occhi/Volto Indossare occhiali protettivi per sostanze chimiche.

Pelle/Corpo In ambiente di laboratorio, indossare, quanto meno, guanti e camici da laboratorio per ridurre al minimo il contatto con la pelle.

Controlli dell'esposizione ambientale Seguire le migliori pratiche per la gestione del sito e per lo smaltimento dei rifiuti.

Legenda delle abbreviazioni

ACGIH = American Conference of Governmental Industrial Hygiene (Conferenza americana degli igienisti industriali governativi)
NIOSH = National Institute of Occupational Safety and Health (Istituto nazionale per la salute e la sicurezza sul lavoro)
OSHA = Occupational Safety and Health Administration (Agenzia per la salute e la sicurezza sul lavoro)
STEL = Short Term Exposure Limits (Limiti di esposizione e breve termine), sono basati su esposizioni di 15 minuti
TWA = Time-Weighted Averages (Medie pesate nel tempo) basate su esposizioni da 8 ore/giorno, 40 ore/settimana

Sezione 9: Proprietà chimico-fisiche

9.1 Informazioni sulle proprietà chimico-fisiche

Descrizione del materiale			
Forma fisica	Liquido	Aspetto/Descrizione	I reagenti sono liquidi inodori, trasparenti e incolori, che vengono stabilizzati principalmente in soluzioni acquose.
Colore	Trasparente	Odore	Inodore
Soglia di odore	Dati mancanti		
Proprietà generali			
Punto di ebollizione	100 °C (212 °F)	Punto di fusione/Punto di congelamento	0 °C (32 °F)
Temperatura di decomposizione	Dati mancanti	pH	Da 8 a 8,3 (solidi e altri reagenti liquidi)
Gravità specifica/densità relativa	Dati mancanti	Solubilità in acqua	Dati mancanti
Viscosità	Dati mancanti	Proprietà esplosive	Dati mancanti
Proprietà ossidanti:	Dati mancanti		
Volatilità			
Pressione di vapore	Dati mancanti	Densità del vapore	Dati mancanti
Tasso di evaporazione	Dati mancanti		
Infiammabilità			
Punto di infiammabilità	Dati mancanti	UEL	Dati mancanti
LEL	Dati mancanti	Autoaccensione	Dati mancanti
Infiammabilità (solido, gas)	Dati mancanti		
Ambientali			
Coefficiente di ripartizione ottanolo-acqua	Dati mancanti		

9.2 Altre informazioni

Non sono state osservate altre proprietà chimico-fisiche.

Sezione 10: Stabilità e reattività

10.1 Reattività

Nessuna reazione pericolosa nota nelle normali condizioni di utilizzo.

10.2 Stabilità chimica

Stabile

10.3 Possibilità di reazioni pericolose

Non si verificherà polimerizzazione pericolosa.

10.4 Condizioni da evitare

Calore, umidità (influenzano la qualità del prodotto)

10.5 Materiali incompatibili

Acidi, agenti ossidanti.

10.6 Prodotti di decomposizione pericolosi

Ossidi di carbonio, ossidi di potassio.

Sezione 11: Informazioni tossicologiche

11.1 Informazioni sugli effetti tossicologici

Componenti		
Cloruro d'ammonio (DAL 20% AL 30%)	12125-02-9	**Tossicità acuta:** Ingestione/Orale-Ratto DL50 • 1650 mg/kg; **Irritazione:** Occhio-Coniglio • 100 mg • Grave irritazione
Carbonato di potassio (DALL'1% AL 5%)	584-08-7	**Tossicità acuta:** Ingestione/Orale-Ratto DL50 • 1870 mg/kg; **Tossicità multidose:** Inalazione-Ratto TCLo • 43 mg/m³ 17 settimane; *Cardiaca*:**variazioni ECG non indicative della tossicità di cui sopra**; *Rene, uretere e vescica*:**altre alterazioni nella composizione delle urine**; *Nutrizionale e metabolica complessiva: alterazioni della chimica o della temperatura*: **K**; **Mutageno:** sintesi non programmata del DNA • Ingestione/Orale-Ratto • 504 g/kg 4 settimane-continuo

Proprietà GHS	**Classificazione**
Tossicità acuta	**UE/CLP**•Dati mancanti **UN GHS 3**•Tossicità acuta - Orale 5 - ATEmix (orale) = 4795 mg/kg **OSHA HCS 2012**•Dati mancanti
Corrosione/Irritazione cutanea	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Grave irritazione/danno oculare	**UE/CLP**•Irritazione oculare 2 **UN GHS 3**•Irritazione oculare 2 **OSHA HCS 2012**•Irritazione oculare 2
Sensibilizzazione cutanea	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Sensibilizzazione respiratoria	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Pericolo derivante dall'inalazione	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Cancerogenicità	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Mutagenesi delle cellule embrionali	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
Tossicità per la riproduzione	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-SE	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti
STOT-RE	**UE/CLP**•Dati mancanti **UN GHS 3**•Dati mancanti **OSHA HCS 2012**•Dati mancanti

Potenziali effetti sulla salute

Inalazione
Acuta (immediata) Nessun dato disponibile
Cronico (ritardato) Nessun dato disponibile
Cute
Acuta (immediata) Nessun dato disponibile
Cronico (ritardato) Nessun dato disponibile
Occhi
Acuto (immediato) Provoca grave irritazione oculare.
Cronico (ritardato) Nessun dato disponibile
Ingestione
Acuto (immediato) Può essere nocivo se ingerito.
Cronico (ritardato) Nessun dato disponibile

Legenda delle abbreviazioni
DL = Dose letale
TC = Toxic Concentration (Concentrazione tossica)

Sezione 12: Informazioni ecologiche

12.1 Tossicità

	CAS	
Kit di prelievo dei campioni di urina Xpert, Kit di prelievo dei campioni di urina Xpert CT/NG	NDD	**Tossicità acquatica-Pesci:** 4 giorni CL50 *Atlantic Silverside* 0,14 mg/L Commenti: Cloruro d'ammonio (12125-02-9) 30 giorni NOEC *Pesce gatto maculato* 0,006 mg/L Commenti: Cloruro d'ammonio (12125-02-9) **Tossicità acquatica-Crostacei:** 2 giorni EC50 *Ostracoda* 0,075-0,126 mg/L Commenti: Cloruro d'ammonio (12125-02-9) 21 giorni NOEC *Cladoceri* 0,05 mg/L Commenti: Cloruro d'ammonio (12125-02-9) **Tossicità acquatica-Alghe e altre piante acquatiche:** 3 giorni EC50 *Alga collana di Nettuno* 0,04-0,1 mg/L Commenti: Cloruro d'ammonio (12125-02-9)

Tossico per gli organismi acquatici. Tossico per gli organismi acquatici con effetti di lunga durata.

12.2 Persistenza e degradabilità

Dati materiale mancanti.

12.3 Potenziale di bioaccumulo

Dati materiale mancanti.

12.4 Mobilità nel suolo

Dati materiale mancanti.

12.5 Risultati della valutazione PBT e vPvB

Non sono state condotte valutazioni PBT e vPvB.

12.6 Altri effetti avversi

Non sono stati trovati studi.

Sezione 13: Considerazioni sullo smaltimento

13.1 Metodi di trattamento dei rifiuti

Rifiuti del prodotto Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

Rifiuti di imballaggio Smaltire contenuto e/o recipiente in conformità con normative locali, regionali, nazionali e/o normative internazionali.

13.2 Altre informazioni

I campioni biologici, tra cui le cartucce esauste, devono essere trattati come materiale in grado di trasmettere agenti infettivi. Rivolgersi al personale addetto allo smaltimento dei rifiuti ambientali del proprio istituto per ottenere informazioni utili sul corretto smaltimento delle cartucce esauste e dei reagenti inutilizzati. Questo materiale può presentare caratteristiche dell'EPA Resource Conservation and Recovery Act (RCRA) sui residui pericolosi che richiedono uno smaltimento specifico. Verificare le normative nazionali e locali perché possono differire dalle normative regionali sullo smaltimento. Le istituzioni al di fuori degli Stati Uniti dovrebbero verificare i requisiti per lo smaltimento dei residui pericolosi del proprio Paese.

Sezione 14: Informazioni sul trasporto

	14.1 Numero ONU	14.2 Nome di spedizione corretto ONU	14.3 Classi di pericolosità per il trasporto	14.4 Gruppo di imballaggio	14.5 Pericoli ambientali
DOT	Non applicabile	Non soggetto a regolamentazione	Non applicabile	Non applicabile	NDD
TDG	UN3082	SOSTANZA PERICOLOSA PER L'AMBIENTE, LIQUIDO, N.A.S. (Cloruro d'ammonio)	9	III	NDD
IMO/IMDG	UN3082	SOSTANZA PERICOLOSA PER L'AMBIENTE, LIQUIDO, N.A.S. (Cloruro d'ammonio)	9	III	NDD
IATA/ICAO	UN3082	SOSTANZA PERICOLOSA PER L'AMBIENTE, LIQUIDO, N.A.S. (Cloruro d'ammonio)	9	III	NDD

14.6 Precauzioni speciali per l'utilizzatore

Nessuna specificata.

14.7 Trasporto alla rinfusa in conformità all'Allegato II di MARPOL 73/78 e al codice IBC

Dati mancanti.

Sezione 15: Informazioni regolatorie

15.1 Normative/legislazione in materia di ambiente, salute e sicurezza specifiche per la sostanza o la miscela

Classificazioni dei rischi SARA Acuta

Inventario						
Componente	**CAS**	**Canada DSL**	**Canada NDSL**	**UE EINECS**	**UE ELNICS**	**TSCA**
Cloruro d'ammonio	12125-02-9	Sì	No	Sì	No	Sì
Carbonato di potassio	584-08-7	Sì	No	Sì	No	Sì

Scheda dati di sicurezza

Data di decorrenza: Febbraio 2020
Sostituisce la versione del: Luglio 2016

Kit di prelievo dei campioni di urina Xpert
Kit di prelievo dei campioni di urina Xpert CT/NG

Canada

Lavoro

Canada - WHMIS - Classificazione delle sostanze

•Carbonato di potassio	584-08-7	D2B, E
•Cloruro d'ammonio	12125-02-9	D2B

Canada - WHMIS - Elenco degli ingredienti

•Carbonato di potassio	584-08-7	1%
•Cloruro d'ammonio	12125-02-9	1%

Ambiente

Canada - CEPA - Elenco sostanze prioritarie

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

Stati Uniti

Lavoro

USA - OSHA - Gestione dei processi di sicurezza - Sostanze chimiche estremamente pericolose

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

USA - OSHA - Prodotti chimici specificamente regolati

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

Ambiente

USA - CAA (Clean Air Act) - 1990 Inquinanti pericolosi per l'aria

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

USA - CERCLA/SARA - Sostanze pericolose e quantità riportabili

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	QR finale 2270 kg; QR finale 5000 lb

USA - CERCLA/SARA - Radionuclidi e quantità riportabili

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose EPCRA RQ

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

USA - CERCLA/SARA - Sezione 302 Sostanze estremamente pericolose TPQ

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

USA - CERCLA/SARA - Sezione 313 - Rapporto sulle emissioni

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

USA - CERCLA/SARA - Sezione 313 - Certificazione chimica PBT

•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

Stati Uniti - California

Ambiente

USA - California - Proposta 65 - Elenco sostanze cancerogene		
•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato
USA - California - Proposta 65 - Tossicità per lo sviluppo		
•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato
USA - California - Proposta 65 - MADL (Maximum Allowable Dose Levels, livelli di dose massimi consentiti)		
•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato
USA - California - Proposta 65 - NSRL (No Significant Risk Levels, nessun livello di rischio significativo)		
•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato
USA - California - Proposta 65 - Tossicità sulla riproduzione - Femminile		
•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato
USA - California - Proposta 65 - Tossicità sulla riproduzione - Maschile		
•Carbonato di potassio	584-08-7	Non elencato
•Cloruro d'ammonio	12125-02-9	Non elencato

15.2 Valutazione della sicurezza chimica

Non è stata eseguita alcuna valutazione della sicurezza chimica.

Sezione 16: Altre informazioni

Frasi pertinenti (codice e testo completo)

H302 - Nocivo se ingerito.

Esclusione/Dichiarazione di responsabilità

Le suddette informazioni si basano su dati a nostra disposizione e ritenuti corretti. Poiché le informazioni possono essere applicate in condizioni che vanno oltre il nostro controllo e che potremmo non conoscere bene, non ci assumiamo nessuna responsabilità per i risultati derivanti dall'uso che ne viene fatto, e tutte le persone che ne usufruiranno devono stabilire gli effetti, le proprietà, le protezioni e lo smaltimento riguardanti ogni singola situazione. Nessuna rappresentazione, garanzia o assicurazione, esplicita o implicita (comprese una garanzia di idoneità o commerciabilità per un particolare scopo), viene fatta per quanto riguarda i materiali, la precisione delle informazioni fornite, i risultati ottenibili dall'uso che ne viene fatto, o i pericoli connessi con l'uso del materiale. L'uso e la manipolazione del materiale devono essere eseguiti con attenzione. Le suddette informazioni sono fornite in buona fede e con la convinzione che siano esatte. A partire dalla data di emissione, vengono fornite tutte le informazioni a disposizione relativamente al trattamento prevedibile del materiale. Tuttavia, in caso di un incidente avverso relativo al prodotto, questa scheda dati di sicurezza non è, e non intende essere, il surrogato della consultazione con personale opportunamente addestrato. Si prega di fornire la dichiarazione di non responsabilità.

Legenda delle abbreviazioni
NDD = Nessun dato disponibile

Ficha de datos de seguridad
Fecha de entrada en vigor: Febrero de 2020
Sustituye a fecha: Julio de 2016

Kit de recogida de muestras de orina Xpert
Kit de recogida de muestras de orina Xpert CT/NG

Sección 1: Identificación de la sustancia/mezcla y del proyecto/empresa

1.1 Identificador del producto

Nombre del producto **Kit de recogida de muestras de orina Xpert, kit de recogida de muestras de orina Xpert CT/NG**

Código del producto CT/NGURINE-50; URINE/A-50

1.2 Usos identificados de la sustancia o mezcla y usos no recomendados

Usos identificados Uso en laboratorio

1.3 Detalles del proveedor de la ficha de datos de seguridad

Fabricante Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Estados Unidos
www.cepheid.com
EE. UU.: techsupport@cepheid.com

Teléfono (general) 1 (888) 838-3222 - EE. UU. (opción 2)

Teléfono (general) 1 (408) 541-4191 - Fuera de EE. UU.

Proveedor Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Suecia
www.cepheidinternational.com
UE: support@cepheideurope.com

Teléfono (general) +33 563 825 319

1.4 Número de teléfono de emergencia

Fabricante + 1 (800) 535-5053 - INFOTRAC - Emergencia (24 h)

Fabricante + 1 (352) 323-3500- Fuera de EE. UU.

Sección 2: Identificación de riesgos

UE/CEE

De acuerdo con: Reglamento (CE) Nº 1272/2008 (CLP)/REACH 1907/2006 [modificado por 453/2010]

2.1 Clasificación de la sustancia o mezcla

CLP La siguiente FDS está destinada exclusivamente al uso en laboratorio del producto final acabado. Contiene componentes líquidos, algunos de los cuales son reactivos y polvos liofilizados almacenados en el cartucho y en una botella Nalgene. Todos los reactivos son líquidos transparentes e incoloros. Las exenciones de revelación de la información de algún componente son conformes al artículo 1(5)(d) del CLP y a la norma 29 CFR 1910.1200(g)(2)(i)(C)(1)y(2).
Irritación ocular 2 - H319

2.2 Elementos de la etiqueta

CLP

ADVERTENCIA

Declaraciones de riesgo	H319 - Provoca irritación ocular grave.
Declaraciones preventivas	
Prevención	P264 - Lavarse concienzudamente tras la manipulación. P280 - Llevar guantes/prendas/gafas/máscara de protección.
Respuesta	P305+P351+P338 - EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. P337+P313 - Si persiste la irritación ocular: Consultar a un médico.

2.3 Otros riesgos

CLP	De acuerdo con el Reglamento (CE) Nº 1272/2008 (CLP), este material se considera peligroso.

SGA de la ONU, revisión 3

De acuerdo con: Sistema Globalmente Armonizado (SGA) de Clasificación y Etiquetado de Productos Químicos de la ONU:
Tercera edición revisada

2.1 Clasificación de la sustancia o mezcla

SGA de la ONU	Toxicidad oral aguda 5 Irritación ocular 2 Peligroso para el medio ambiente acuático Agudo 1 Peligroso para el medio ambiente acuático Crónico 1

2.2 Elementos de la etiqueta

SGA de la ONU

ADVERTENCIA

Declaraciones de riesgo	Nocivo en caso de ingestión. Provoca irritación ocular grave. Muy tóxico para los organismos acuáticos. Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.
Declaraciones preventivas	
Prevención	Lavarse concienzudamente tras la manipulación. Evitar su liberación al medio ambiente. Llevar guantes/prendas/gafas/máscara de protección.

Respuesta	EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. Si persiste la irritación ocular: Consultar a un médico. Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico en caso de malestar. Recoger el vertido.
Almacenamiento/eliminación	Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

2.3 Otros riesgos

SGA de la ONU	De acuerdo con el Sistema Globalmente Armonizado de Clasificación y Etiquetado de Productos Químicos (SGA), este producto se considera peligroso.

Estados Unidos (EE. UU.)
De acuerdo con: OSHA 29 CFR 1910.1200 HCS

2.1 Clasificación de la sustancia o mezcla

HCS 2012 de la OSHA	Irritación ocular 2

2.2 Elementos de la etiqueta

HCS 2012 de la OSHA

ADVERTENCIA

Declaraciones de riesgo	Provoca irritación ocular grave.
Declaraciones preventivas	
Prevención	Lavarse concienzudamente tras la manipulación. Llevar guantes/prendas/gafas/máscara de protección.
Respuesta	EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. Si persiste la irritación ocular: Consultar a un médico.

2.3 Otros riesgos

HCS 2012 de la OSHA	De acuerdo con el reglamento de los Estados Unidos (29 CFR 1910.1200 - Estándar de Comunicación de Riesgos), este producto se considera peligroso.

Canadá
De acuerdo con: WHMIS

2.1 Clasificación de la sustancia o mezcla

WHMIS	Otros efectos tóxicos - D2B

2.2 Elementos de la etiqueta

WHMIS

Otros efectos tóxicos - D2B

2.3 Otros riesgos

WHMIS

El producto mencionado se considera peligroso en Canadá, de acuerdo con el Sistema de Información de Materiales Peligrosos en el Lugar de Trabajo (WHMIS).

2.4 Información adicional

Todos los demás reactivos, microesferas y otros constituyentes presentan concentraciones inferiores al 1% en la mezcla o no son considerados peligrosos según los reglamentos de comunicación de riesgos de EE. UU. (29 CFR 1910.1200), las directivas para la clasificación y el etiquetado de sustancias y mezclas de la UE y el Sistema Globalmente Armonizado de clasificación y etiquetado de sustancias y mezclas.

Sección 3: Composición/información de los ingredientes

3.1 Sustancias

El material no cumple con los criterios de clasificación de sustancias.

3.2 Mezclas

Composición					
Nombre del producto químico	**Identificadores**	**%**	**LD50/LC50**	**Clasificaciones de acuerdo con el reglamento/directiva**	**Comentarios**
Cloruro de amonio	**CAS:** 12125-02-9 **Numero CE:** 235-186-4 **Índice UE:** 017-014-00-8	20% A 30%	Ingestión/Oral-Rata LD50 • 1650 mg/kg	**CLP UE:** Anexo VI, Tabla 3.1: Tox. aguda 4 *, H302; Irrit. ocular 2, H319 **SGA de la ONU, revisión 3:** Tox. aguda 4 (oral); Irrit. ocular 2; Acuática aguda 1; Acuática crónica 1 **HCS 2012 de la OSHA:** Tox. aguda 4 (oral); Irrit. ocular 2	No hay datos disponibles
Carbonato potásico	**CAS:**584-08-7 **Numero CE:** 209-529-3	1% A 5%	Ingestión/Oral-Rata LD50 • 1870 mg/kg	**CLP UE:** Tox. aguda 4, H302 **SGA de la ONU, revisión 3:** Tox. aguda 4 (oral); Irrit. ocular 2B **HCS 2012 de la OSHA:** Tox. aguda 4 (oral); Irrit. ocular 2B	No hay datos disponibles

Acceda a la Sección 16 para consultar el texto completo de las declaraciones de riesgo.

Sección 4: Medidas de primeros auxilios

4.1 Descripción de las medidas de primeros auxilios

Inhalación

No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Traslade a la persona al aire libre. Si la respiración resulta difícil, administre oxígeno. No utilice el método de boca a boca si la víctima ha inhalado la sustancia; proporcione respiración artificial con la ayuda de una máscara de bolsillo equipada con una válvula de una sola vía u otro dispositivo médico de respiración adecuado. Si la persona no respira, proporcione respiración artificial.

Piel	No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Ante un contacto menor con la piel, evite la difusión del material sobre la piel no afectada. Si entra en contacto con la sustancia, enjuague inmediatamente la piel con agua durante al menos 20 minutos. Retire y aísle la ropa contaminada.
Ojo	No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. Si entra en contacto con la sustancia, enjuague inmediatamente los ojos con agua durante al menos 20 minutos. Si persiste la irritación ocular: Consultar a un médico.
Ingestión	No se prevé la necesidad de aplicar primeros auxilios si el material se utiliza en condiciones normales y de la forma recomendada. En caso de ingestión, enjuague la boca con agua (solo si la persona está consciente). NO provoque el vómito. No utilice el método de boca a boca si la víctima ha ingerido la sustancia. En caso de ingestión, solicite atención médica inmediatamente.

4.2 Síntomas y efectos más importantes, tanto agudos como retardados

Consulte la Sección 11 - Información toxicológica.

4.3 Indicación de cualquier atención médica inmediata y tratamiento especial necesarios

Notas para el médico	Todos los tratamientos deben basarse en señales y síntomas observados en el paciente. Considere si puede haberse producido una sobreexposición a otros materiales distintos de este producto.

Sección 5: Medidas antiincendios

5.1 Medios de extinción

Medios de extinción adecuados	INCENDIOS MAYORES: Polvo químico seco, CO_2, espuma resistente al alcohol o agua pulverizada. INCENDIOS MENORES: Polvo químico seco, CO_2 o agua pulverizada.
Medios de extinción inadecuados	No hay datos disponibles

5.2 Riesgos especiales procedentes de la sustancia o mezcla

Riesgos de incendio y explosión inusuales	Puede emitir vapores tóxicos de óxidos de carbono y óxidos de nitrógeno.
Productos de combustión peligrosa	No hay datos disponibles

5.3 Consejos para el personal antiincendios

El traje de protección estándar del personal antiincendios proporciona protección limitada EXCLUSIVAMENTE contra el fuego; no resulta efectivo ante vertidos donde es posible el contacto directo con la sustancia.
Utilice un traje de protección química específicamente recomendado por el fabricante. Puede proporcionar poca o ninguna protección térmica.
Utilice un equipo de respiración autónomo (ERA) de presión positiva.
INCENDIOS MENORES: Mueva los contenedores del área del incendio si la operación no conlleva riesgos.

Sección 6: Medidas en caso de liberación accidental

6.1 Precauciones personales, equipamiento protector y procedimientos de emergencia

Precauciones personales	En caso de romperse un cartucho, pueden aplicarse estas precauciones personales. Utilice un traje de protección adecuado. No camine a través del material vertido. No toque los contenedores dañados ni los materiales vertidos a menos que utilice un traje de protección adecuado. Ventile las áreas cerradas.
Procedimientos de emergencia	Se espera que no sea necesario aplicar procedimientos de emergencia si el material se utiliza bajo condiciones normales y del modo recomendado.

6.2 Precauciones medioambientales

Evite la entrada en alcantarillas, vías fluviales, sótanos y espacios cerrados.

6.3 Métodos y materiales de contención y limpieza

Medidas de contención y limpieza	Para vertidos menores, utilice guantes y absorba el vertido con una toalla de papel. No deseche materiales vertidos por el desagüe.

6.4 Referencia a otras secciones

Consulte la Sección 8 - Controles de exposición / protección personal y la Sección 13 - Consideraciones de eliminación.

Sección 7: Manipulación y almacenamiento

7.1 Precauciones para la manipulación segura

Manipulación	No se necesita ninguna manipulación especial. En caso de romperse un cartucho, evite el contacto con los reactivos vertidos. Evite el contacto con la piel y los ojos.

7.2 Condiciones para el almacenamiento seguro, incluidas posibles incompatibilidades

Almacenamiento	Almacénelos de acuerdo con las indicaciones de su etiqueta. Mantenga el contenedor/embalaje bien cerrado en un lugar fresco y ventilado. Mantenga el producto alejado de materiales incompatibles.

7.3 Usos finales específicos

Consulte la Sección 1.2 - Usos identificados relevantes.

Sección 8: Controles de exposición / protección personal

8.1 Parámetros de control

Directrices/límites de exposición			
	Resultado	**ACGIH**	**NIOSH**
Cloruro de amonio (12125-02-9)	STELs	20 mg/m3 STEL (vapor)	20 mg/m3 STEL (vapor)
	TWAs	10 mg/m3 TWA (vapor)	10 mg/m3 TWA (vapor)

8.2 Controles de exposición

Controles/medidas de ingeniería
Es necesaria una buena ventilación general. La tasa de ventilación debe corresponder a las condiciones. Si es posible, utilice recintos de procesamiento, ventilación local u otros controles de ingeniería para mantener los niveles del aire por debajo de los límites de exposición recomendados. Si los límites de exposición no se han establecido, mantenga los niveles del aire a un nivel aceptable.

Equipo de protección individual

Respiratorios
Siga los reglamentos para máscaras de la OSHA incluidas en el estándar 29 CFR 1910.134 y en el estándar europeo EN 149. Utilice una máscara aprobada por la NIOSH/MSHA o la norma europea EN 149 si se superan los límites de exposición o se experimentan síntomas.

Ocular/facial
Utilice gafas de protección contra salpicaduras químicas.

Piel/cuerpo
En el laboratorio, utilice guantes y bata para minimizar el contacto con la piel.

Controles de exposición en el medio ambiente
Siga las buenas prácticas para administrar el centro y eliminar residuos.

Clave de abreviaturas
ACGIH = Conferencia Estadounidense de Higienistas Industriales de la Administración
NIOSH = Instituto Nacional para la Seguridad y Salud Ocupacional
OSHA = Administración de Seguridad y Salud Ocupacional
STEL = Los límites de exposición a corto plazo se basan en exposiciones de 15 minutos
TWA = Los promedios de tiempo ponderado se basan en exposiciones durante 8 h/día y 40 h/semana

Sección 9: Propiedades físicas y químicas

9.1 Información sobre las propiedades físicas y químicas

Descripción del material			
Forma física	Líquido	Aspecto/Descripción	Los reactivos son líquidos transparentes, incoloros e inodoros, que se tamponan principalmente en soluciones acuosas.
Color	Transparente	Olor	Inodoro
Umbral de olor	Faltan datos		
Propiedades generales			
Punto de ebullición	100 °C (212 °F)	Punto de fusión / punto de congelación	0 °C (32 °F)
Temperatura de descomposición	Faltan datos	pH	8 a 8,3 (sólidos y otros reactivos líquidos)
Gravedad específica / densidad relativa	Faltan datos	Hidrosolubilidad	Faltan datos
Viscosidad	Faltan datos	Propiedades explosivas	Faltan datos
Propiedades oxidantes:	Faltan datos		
Volatilidad			
Presión del vapor	Faltan datos	Densidad del vapor	Faltan datos
Tasa de evaporación	Faltan datos		
Inflamabilidad			
Punto de inflamación	Faltan datos	UEL	Faltan datos
LEL	Faltan datos	Autoignición	Faltan datos
Inflamabilidad (sólido, gas)	Faltan datos		
Medioambiental			
Coeficiente de reparto octanol/agua	Faltan datos		

9.2 Información adicional

No se han anotado parámetros físicos o químicos adicionales.

Sección 10: Estabilidad y reactividad

10.1 Reactividad

No se conocen reacciones peligrosas bajo condiciones normales de uso.

10.2 Estabilidad del producto químico

Estable

10.3 Posibilidad de reacciones peligrosas

No ocurrirá polimerización peligrosa.

10.4 Condiciones que deben evitarse

Calor y humedad (afectan a la calidad del producto)

10.5 Materiales incompatibles

Ácidos, agentes oxidantes.

10.6 Productos de descomposición peligrosos

Óxidos de carbono, óxidos de potasio.

Sección 11: Información toxicológica

11.1 Información sobre efectos toxicológicos

Componentes		
Cloruro de amonio (20% A 30%)	12125-02-9	**Toxicidad aguda:** Ingestión/Oral-Rata LD50 • 1650 mg/kg; **Irritación:** Ojo-Conejo • 100 mg • Irritación grave
Carbonato potásico (1% A 5%)	584-08-7	**Toxicidad aguda:** Ingestión/Oral-Rata LD50 • 1870 mg/kg; **Toxicidad multidosis:** Inhalación-Rata TCLo • 43 mg/m³ 17 semana(s); *Cardíaco*:**Cambios en el ECG sin diagnóstico anterior**; *Riñón, uréter y vejiga*:**Otros cambios en la composición de la orina**; *Nutricional y metabólico importante:Cambios térmicos o químicos*: **K**; **Mutágeno:** Síntesis de ADN no programada • Ingestión/Oral-Rata • 504 g/kg (4 semana(s)-Continuo)

Propiedades del SGA	Clasificación
Toxicidad aguda	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Toxicidad aguda - Oral 5 - ATEmix (oral) = 4795 mg/kg **HCS 2012 de la OSHA**•Faltan datos
Corrosión/irritación cutánea	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Daño/irritación ocular grave	**UE/CLP**•Irritación ocular 2 **SGA de la ONU 3**•Irritación ocular 2 **HCS 2012 de la OSHA**•Irritación ocular 2
Sensibilización cutánea	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Sensibilización respiratoria	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Riesgo de aspiración	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Carcinogenicidad	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Mutagenicidad de células germinales	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
Toxicidad para la reproducción	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-SE	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos
STOT-RE	**UE/CLP**•Faltan datos **SGA de la ONU 3**•Faltan datos **HCS 2012 de la OSHA**•Faltan datos

Efectos potenciales en la salud

Inhalación
Agudo (inmediato) No hay datos disponibles
Crónico (retardado) No hay datos disponibles
Piel
Agudo (inmediato) No hay datos disponibles
Crónico (retardado) No hay datos disponibles
Ojo
Agudo (inmediato) Provoca irritación ocular grave.
Crónico (retardado) No hay datos disponibles
Ingestión
Agudo (inmediato) Ingestión posiblemente dañina.
Crónico (retardado) No hay datos disponibles

Clave de abreviaturas
LD = Dosis letal
TC = Concentración tóxica

Sección 12: Información ecológica

12.1 Toxicidad

	CAS	
Kit de recogida de muestras de orina Xpert, kit de recogida de muestras de orina Xpert CT/NG	No hay datos disponibles	**Toxicidad acuática-Peces:** 4 día(s) LC50 *Sardina atlántica* 0,14 mg/L Comentarios: Cloruro de amonio (12125-02-9) 30 días(s) NOEC *Pez gato americano* 0,006 mg/L Comentarios: Cloruro de amonio (12125-02-9) **Toxicidad acuática-Crustáceos:** 2 día(s) EC50 *Ostracoda* 0,075-0,126 mg/L Comentarios: Cloruro de amonio (12125-02-9) 21 días(s) NOEC *Pulga de agua* 0,05 mg/L Comentarios: Cloruro de amonio (12125-02-9) **Toxicidad acuática-Algas y otra(s) planta(s) acuática(s):** 3 día(s) EC50 *Alga collar de Neptuno* 0,04-0,1 mg/L Comentarios: Cloruro de amonio (12125-02-9)

Tóxico para los organismos acuáticos. Tóxico para los organismos acuáticos, con efectos nocivos duraderos.

12.2 Persistencia y degradabilidad

Faltan datos de material.

12.3 Potencial bioacumulativo

Faltan datos de material.

12.4 Movilidad en el suelo

Faltan datos de material.

12.5 Resultados de la evaluación de PBT y mPmB

No se ha realizado ninguna valoración de PBT y mPmB.

12.6 Otros efectos adversos

No se han encontrado estudios.

Sección 13: Consideraciones sobre la eliminación

13.1 Métodos de tratamiento de residuos

Residuos de productos Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

Residuos de embalaje Deseche el contenido y/o el contenedor conforme a los reglamentos locales, regionales, nacionales e internacionales.

13.2 Información adicional

Los especímenes biológicos, incluidos cartuchos usados, deben tratarse como posibles transmisores de agentes infecciosos. Consulte con el personal de residuos medioambientales de su institución el procedimiento correcto de eliminación de cartuchos utilizados y de reactivos sin utilizar. Este material puede mostrar características de residuos peligrosos según la Ley de Recuperación y Conservación de Recursos (RCRA) de la EPA y necesitar requisitos específicos para su eliminación. Compruebe los reglamentos locales y estatales, ya que pueden ser diferentes a los reglamentos de eliminación federales. Las instituciones externas a EE. UU. deben comprobar los requisitos de eliminación de residuos peligrosos de su país.

Sección 14: Información de transporte

	14.1 Número ONU	14.2 Designación oficial de transporte de la ONU	14.3 Clases de riesgo de transporte	14.4 Grupo de embalaje	14.5 Riesgos para el medioambiente
DOT	No aplica	No regulado	No aplica	No aplica	No hay datos disponibles
TDG	UN3082	SUSTANCIA PELIGROSA PARA EL MEDIO AMBIENTE, LÍQUIDA, SIN OTRAS ESPECIFICACIONES (cloruro de amonio)	9	III	No hay datos disponibles
IMO/IMDG	UN3082	SUSTANCIA PELIGROSA PARA EL MEDIO AMBIENTE, LÍQUIDA, SIN OTRAS ESPECIFICACIONES (cloruro de amonio)	9	III	No hay datos disponibles
IATA/ICAO	UN3082	SUSTANCIA PELIGROSA PARA EL MEDIO AMBIENTE, LÍQUIDA, SIN OTRAS ESPECIFICACIONES (cloruro de amonio)	9	III	No hay datos disponibles

14.6 Precauciones especiales para el usuario

Ninguno especificado.

14.7 Transporte a granel de acuerdo con el Anexo II del MARPOL 73/78 y el código IBC

Faltan datos.

Sección 15: Información reglamentaria

15.1 Legislación/reglamentos de seguridad, salud y medio ambiente específicos para la sustancia o mezcla

Clasificaciones de riesgo de la ley SARA Agudo

Inventario						
Componente	**CAS**	**DSL de Canadá**	**NDSL de Canadá**	**EINECS de la UE**	**ELNICS de la UE**	**TSCA**

Cloruro de amonio	12125-02-9	Sí	No	Sí	No	Sí
Carbonato potásico	584-08-7	Sí	No	Sí	No	Sí

Canadá

Mano de obra

Canadá - WHMIS - Clasificación de sustancias

•Carbonato potásico	584-08-7	D2B, E
•Cloruro de amonio	12125-02-9	D2B

Canadá - WHMIS - Lista de divulgación de ingredientes

•Carbonato potásico	584-08-7	1%
•Cloruro de amonio	12125-02-9	1%

Medio ambiente

Canadá - CEPA - Lista de sustancias prioritarias

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

Estados Unidos

Mano de obra

EE. UU. - OSHA - Administración de seguridad de procesos - Productos químicos muy peligrosos

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

EE. UU. - OSHA - Productos químicos regulados de manera específica

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

Medio ambiente

EE. UU. - CAA (Clean Air Act) - 1990 Contaminantes peligrosos del aire

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

EE. UU. - CERCLA/SARA - Sustancias peligrosas y sus cantidades declarables

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	Cantidad notificable final: 2270 kg; cantidad notificable final: 5000 libras

EE. UU. - CERCLA/SARA - Radionucleidos y sus cantidades declarables

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades declarables de sustancias extremadamente peligrosas según la EPCRA

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

EE. UU. - CERCLA/SARA - Sección 302 Cantidades para la planificación de umbrales de sustancias extremadamente peligrosas

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

EE. UU. - CERCLA/SARA - Sección 313 - Informes de emisión

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

EE. UU. - CERCLA/SARA - Sección 313 - Lista de productos químicos PBT

•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

Estados Unidos - California

Medio ambiente

EE. UU. - California - Proposición 65 - Lista de productos cancerígenos		
•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado
EE. UU. - California - Proposición 65 - Toxicidad en el desarrollo		
•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado
EE. UU. - California - Proposición 65 - Niveles máximos de dosis permitidos (MADL)		
•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado
EE. UU. - California - Proposición 65 - Sin niveles de riesgo significativos (NSRL)		
•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado
EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Mujeres		
•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado
EE. UU. - California - Proposición 65 - Toxicidad en la reproducción - Hombres		
•Carbonato potásico	584-08-7	No listado
•Cloruro de amonio	12125-02-9	No listado

15.2 Evaluación de la seguridad química

No se ha llevado a cabo ninguna evaluación de seguridad química.

Sección 16: Información adicional

Frases pertinentes (código y texto completo)

H302 - Nocivo en caso de ingestión.

Declaración/ descargo de responsabilidad

La información anterior está basada en los datos que tenemos y la consideramos correcta. Debido a que la información puede aplicarse bajo condiciones externas a nuestro control y con las que podemos no estar familiarizados, no asumimos ninguna responsabilidad por los resultados de su uso, y todas las personas que la reciban deberán determinar por sí mismas los efectos, propiedades, protecciones y eliminación correspondientes a sus condiciones particulares. No se efectúa ninguna representación ni garantía, expresa o implícita (incluida ninguna garantía de adecuación o comerciabilidad para un objetivo concreto) respecto a los materiales, la precisión de esta información, los resultados obtenidos de su uso ni los riesgos relacionados con dicho uso del material. Tenga precaución al manipular y utilizar el material. La información superior se considera precisa y se ofrece de buena fe. Proporcionamos toda la información relacionada con la manipulación prevista del material en la fecha de publicación. Sin embargo, en caso de ocurrir un incidente adverso asociado a este producto, esta ficha de datos de seguridad no es ni debe utilizarse como sustituto de la consulta con personal formado adecuadamente. Proporcione su descargo de responsabilidad.

Ficha de dados de segurança
Data de entrada em vigor: Fevereiro de 2020
Data de substituição: Julho de 2016

Xpert Urine Specimen Collection Kit
Xpert CT/NG Urine Specimen Collection Kit

Secção 1: Identificação da substância/mistura e da empresa/projeto

1.1 Identificador do Produto

Nome do Produto	**Xpert Urine Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit**
Código do produto	CT/NGURINE-50; URINE/A-50

1.2 Usos relevantes da substância ou mistura identificados, e usos não recomendados

Uso(s) relevante(s) identificado(s)	Utilização laboratorial

1.3 Detalhes do fornecedor da ficha de dados de segurança do material

Fabricante		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 Estados Unidos da América www.cepheid.com EUA: techsupport@cepheid.com
	Telefone (Geral)	1 (888) 838-3222 - Opção 2 (EUA)
	Telefone (Geral)	1 (408) 541-4191 - Fora dos EUA
Fornecedor		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Suécia www.cepheidinternational.com UE: support@cepheideurope.com
	Telefone (Geral)	+33 563 825 319

1.4 Número de telefone de emergência

Fabricante	+ 1 (800) 535-5053 - INFOTRAC - Emergência durante 24 h
Fabricante	+ 1 (352) 323-3500- Fora dos EUA

Secção 2: Identificação dos riscos

UE/CEE

Segundo: Regulamentação (CE) N.º 1272/2008 (CLP)/REACH 1907/2006 [alterada pela 453/2010]

2.1 Classificação da substância ou mistura

CLP	A seguinte ficha de dados de segurança destina-se apenas ao produto final acabado usado em laboratório. Contém componentes líquidos, alguns dos quais sob a forma de pós liofilizados e reagentes que se encontram no cartucho e numa garrafa Nalgene. Todos os reagentes são líquidos incolores e transparentes. As isenções para a divulgação de informação sobre alguns componentes estão em conformidade com o artigo 1(5)(d) do CLP e a secção 29 1910.1200(g)(2)(i)(C)(1)&(2) do CFR. Irritação ocular 2 — H319

2.2 Elementos do rótulo

CLP

AVISO

Declarações de risco H319 — Provoca irritação ocular grave

Declarações de precaução

Prevenção P264 — Lavar cuidadosamente após manuseamento.
P280 — Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial.

Resposta P305 + P351 + P338 — SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar.
P337 + P313 — Caso a irritação ocular persista: consulte um médico.

2.3 Outros riscos

CLP Este material é considerado perigoso de acordo com a Regulamentação (CE) N.º 1272/2008 (CLP).

GHS da ONU Revisão 3

Segundo: Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS) da ONU: Terceira edição revista

2.1 Classificação da substância ou mistura

GHS da ONU
Toxicidade oral aguda 5
Irritação ocular 2
Perigoso para o ambiente aquático Agudo 1
Perigoso para o ambiente aquático Crónico 1

2.2 Elementos do rótulo

GHS da ONU

AVISO

Declarações de risco
Possibilidade de ser nocivo por ingestão
Provoca irritação ocular grave
Muito tóxico para a vida aquática
Muito tóxico para a vida aquática com efeitos duradouros

Declarações de precaução

Prevenção
Lavar cuidadosamente após manuseamento.
Evitar a libertação para o ambiente.
Usar luvas de proteção/vestuário de proteção/proteção ocular/proteção facial.

Resposta	SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar. Caso a irritação ocular persista: consulte um médico. Caso sinta indisposição, contacte um CENTRO DE INFORMAÇÃO ANTIVENENOS ou um médico. Recolher derrame.
Armazenamento/Eliminação	Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

2.3 Outros riscos

GHS da ONU Este produto é considerado perigoso de acordo com o Sistema Mundial Harmonizado de Classificação e Rotulagem de Produtos Químicos (GHS).

Estados Unidos da América (EUA)
Segundo: OSHA 29 CFR 1910.1200 HCS

2.1 Classificação da substância ou mistura

OSHA HCS 2012 Irritação ocular 2

2.2 Elementos do rótulo

OSHA HCS 2012

AVISO

Declarações de risco	Provoca irritação ocular grave
Declarações de precaução	
Prevenção	Lavar cuidadosamente após manuseamento. Usar luvas de proteção/vestuário de proteção/proteção ocular/proteção facial.
Resposta	SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continue a enxaguar. Caso a irritação ocular persista: consulte um médico.

2.3 Outros riscos

OSHA HCS 2012 Este produto é considerado perigoso ao abrigo da Regulamentação dos Estados Unidos da América (Norma sobre Comunicação de Perigos - 29 CFR 1910.1200).

Canadá
Segundo: WHMIS

2.1 Classificação da substância ou mistura

WHMIS Outros efeitos tóxicos — D2B

2.2 Elementos do rótulo

WHMIS

Outros efeitos tóxicos — D2B

2.3 Outros riscos

WHMIS

No Canadá, o produto acima referido é considerado perigoso ao abrigo do Sistema de Informação de Materiais Perigosos no Local de Trabalho (WHMIS).

2.4 Outras informações

Todos os restantes reagentes, esferas e outros constituintes da mistura estão em concentrações inferiores a 1% ou não são considerados perigosos ao abrigo das regulamentações de comunicação de perigos (29 CFR 1910.1200), das diretivas da UE para a classificação e rotulagem de substâncias ou misturas ou do Sistema Mundial Harmonizado para a classificação e rotulagem de substâncias ou misturas.

Secção 3: Composição/informações sobre os ingredientes

3.1 Substâncias

O material não cumpre os critérios de uma substância.

3.2 Misturas

Composição					
Nome do produto químico	**Identificadores**	**%**	**LD50/LC50**	**Classificações de acordo com regulamentos/diretivas**	**Comentários**
Cloreto de amónio	**CAS:** 12125-02-9 **Número na CE:** 235-186-4 **Índice UE:** 017-014-00-8	20% A 30%	Ingestão/Oral-Rato LD50 • 1650 mg/kg	**UE CLP:** Anexo VI, Tabela 3.1: Tox. aguda 4 *, H302; Irrit. olhos 2, H319 **GHS da ONU Revisão 3:** Tox. aguda 4 (oral); Irrit. olhos 2; Toxicidade aguda em ambiente aquático 1; Aquática Crónica 1 **OSHA HCS 2012:** Tox. aguda 4 (oral); Irrit. olhos 2	NDA
Carbonato de potássio	**CAS:**584-08-7 **Número na CE:** 209-529-3	1% A 5%	Ingestão/Oral-Rato LD50 • 1870 mg/kg	**UE CLP:** Tox. aguda 4, H302 **GHS da ONU Revisão 3:** Tox. aguda 4 (oral); Irrit. olhos 2B **OSHA HCS 2012:** Tox. aguda 4 (oral); Irrit. olhos 2B	NDA

Consultar o texto completo das declarações de perigo na Secção 16.

Secção 4: Medidas de primeiros socorros

4.1 Descrição das medidas de primeiros socorros

Inalação

Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Mover a vítima para o ar livre. Administrar oxigénio se a respiração estiver difícil. Não usar o método boca-a-boca se a vítima tiver inalado a substância; ministre respiração artificial com o auxílio de uma máscara de bolso equipada com uma válvula de 1 via ou outro dispositivo médico de respiração adequado. Administrar respiração artificial se a vítima não estiver a respirar.

Pele	Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Para um pequeno contacto com a pele, evitar espalhar o material pela pele não afetada. Em caso de contacto com a substância, lavar imediatamente a pele com água corrente por pelo menos 20 minutos. Despir e isolar a roupa contaminada.
Olhos	Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de contacto com a substância, lavar imediatamente os olhos com água corrente por pelo menos 20 minutos. Caso a irritação ocular persista: consulte um médico.
Ingestão	Não devem ser necessários primeiros socorros se o material for utilizado nas condições normais e conforme recomendado. Em caso de ingestão, lavar a boca com água (apenas se a pessoa estiver consciente). NÃO provocar o vómito. Não usar o método boca-a-boca se a vítima tiver ingerido a substância. Em caso de ingestão, consultar um médico imediatamente.

4.2 Sintomas e efeitos mais importantes, tanto agudos quanto retardados

Consultar a Secção 11 — Informação Toxicológica.

4.3 Indicação de qualquer cuidado médico imediato e tratamento especial necessários

Notas para o Médico	Todos os tratamentos devem basear-se nos sinais e sintomas de perturbações observados no paciente. Deve ser considerada a possibilidade de sobrexposição a outros materiais além deste produto.

Secção 5: Medidas de combate a incêndios

5.1 Meios de extinção

Meios de extinção adequados	GRANDES INCÊNDIOS: Produto químico seco, CO2, espuma resistente ao álcool ou água pulverizada. PEQUENOS INCÊNDIOS: Produto químico seco, CO2 ou água pulverizada.
Meios de extinção inadequados	Sem dados disponíveis

5.2 Riscos especiais provocados pela substância ou mistura

Riscos de Incêndios e Explosões Incomuns	Pode emitir vapores tóxicos de óxidos de carbono, óxidos de azoto.
Produtos de combustão de risco	Sem dados disponíveis

5.3 Conselhos para bombeiros

Roupas protetoras estruturais de bombeiros fornecem APENAS proteção limitada em caso de incêndio; não são eficientes em situações de derramamentos, onde é possível o contacto direto com a substância.
Usar roupa protetora contra produtos químicos que seja especificamente recomendada pelo fabricante. Poderá fornecer proteção térmica mínima ou nenhuma proteção.
Usar aparelho de respiração autónomo de pressão positiva (SCBA).
PEQUENOS INCÊNDIOS: Se não houver perigos, mover os recipientes da área de incêndio.

Secção 6: Medidas contra Libertação Acidental

6.1 Precauções individuais, equipamento protetor e procedimentos em emergências

Precauções pessoais	No caso de um cartucho se partir, aplicam-se estas precauções de proteção individual. Usar vestuário de proteção adequado. Não andar sobre material derramado. Não tocar em recipientes danificados ou material derramado a não ser que esteja a usar vestuário de proteção adequado. Ventilar áreas fechadas.
Procedimentos de emergência	Não se prevê a necessidade de procedimentos de emergência se o material for usado em condições normais e de acordo com as recomendações.

6.2 Precauções ambientais

Evitar a entrada em cursos de água, esgotos, caves ou áreas confinadas.

6.3 Métodos e material para contenção e limpeza

Medidas de contenção/limpeza	Em caso de derrames pequenos, usar luvas e absorver o derrame com papel absorvente. Não eliminar os materiais derramados através do sistema de esgotos.

6.4 Referências para outras secções

Consultar a Secção 8 — Controlo da Exposição/Proteção Individual e a Secção 13 — Considerações relativas à eliminação.

Secção 7: Manuseamento e armazenamento

7.1 Precauções para o manuseamento seguro

Manuseamento	Não necessita de manuseamento especial. Se o cartucho se partir, evitar o contacto com os reagentes derramados. Evitar o contacto com a pele e os olhos.

7.2 Condições para armazenamento seguro, incluindo quaisquer incompatibilidades

Armazenamento	Armazenar de acordo com a documentação do produto. Guardar o recipiente/ embalagem bem fechado em local fresco e bem ventilado. Manter afastado de materiais incompatíveis.

7.3 Utilização(ões) Final(is) Específica(s)

Consultar a Secção 1.2 — Uso(s) final(is) específico(s).

Secção 8: Controlos e exposição/proteção individual

8.1 Parâmetros de controlo

Limites de Exposição/Orientações			
	Resultado	**ACGIH**	**NIOSH**
Cloreto de amónio (12125-02-9)	STEL	20 mg/m3 STEL (fumo)	20 mg/m3 STEL (fumo)
	TWA	10 mg/m3 TWA (fumo)	10 mg/m3 TWA (fumo)

8.2 Controlos de exposição

Medidas/Controlos de Engenharia
Deve usar-se uma boa ventilação geral. Os níveis de ventilação devem estar adequados às condições. Se aplicável, usar confinamento de processos, ventilação por exaustão local ou outro controlo técnico para manter os níveis de partículas disseminadas por via aérea em suspensão abaixo dos limites de exposição recomendados. Caso não tenham sido definidos limites, manter os níveis destas partículas em suspensão num nível aceitável.

Equipamento de Proteção Individual

Respiratório
Seguir as regulamentações da máscara OSHA que se encontram na norma 29 CFR 1910.134 ou na Norma Europeia EN 149. Em caso de ultrapassagem dos limites de exposição ou da ocorrência de sintomas, usar um aparelho de respiração aprovado pelo NIOSH/MSHA ou pela Norma Europeia EN 149.

Olhos/Face
Usar óculos de proteção contra salpicos de produtos químicos.

Pele/Corpo
Em ambiente laboratorial, usar, pelo menos, luvas e bata para minimizar o contacto com a pele.

Controlos Ambientais de Exposição
Seguir as melhores práticas para gestão do local e eliminação dos resíduos.

Chave para abreviaturas
ACGIH = Conferência de Higiene Industrial Governamental (EUA)
NIOSH = Instituto Nacional de Saúde e Segurança no Trabalho
OSHA = Agência para a Segurança e Saúde no Trabalho
STEL = Os limites de exposição de curta duração baseiam-se em exposições de 15 minutos
TWA = A Média Ponderada por tempo tem por base a exposição 8 h/dia, 40 h/semana

Secção 9: Propriedades físicas e químicas

9.1 Informações sobre Propriedades Físicas e Químicas

Descrição do material			
Forma física	Líquido	Aspeto/Descrição	Os reagentes são líquidos transparentes e incolores, inodoros, que são, principalmente, tamponados em soluções aquosas.
Cor	Transparente	Odor	Inodoro
Limiar do Odor	Dados em falta		
Propriedades gerais			
Ponto de ebulição	100 °C (212 °F)	Ponto de fusão/Ponto de congelamento	0 °C (32 °F)
Temperatura de decomposição	Dados em falta	pH	8 a 8,3 (sólidos e outros reagentes líquidos)
Gravidade específica/Densidade relativa	Dados em falta	Solubilidade em água	Dados em falta
Viscosidade	Dados em falta	Propriedades explosivas	Dados em falta
Propriedades Oxidantes:	Dados em falta		
Volatilidade			
Pressão do vapor	Dados em falta	Densidade do vapor	Dados em falta
Taxa de evaporação	Dados em falta		
Inflamabilidade			
Ponto de inflamação	Dados em falta	UEL	Dados em falta
LEL	Dados em falta	Autoignição	Dados em falta
Inflamabilidade (sólido/gasoso)	Dados em falta		
Ambiental			
Coeficiente de partição octanol/água	Dados em falta		

9.2 Outras Informações

Não foram observados parâmetros físico-químicos adicionais.

Secção 10: Estabilidade e reatividade

10.1 Reatividade

Desconhecida reação perigosa em condições normais de utilização.

10.2 Estabilidade química

Estável

10.3 Possibilidade de reações perigosas

Não haverá polimerização perigosa.

10.4 Condições a evitar

Calor, humidade (que afeta a qualidade do produto)

10.5 Materiais incompatíveis

Ácidos, agentes oxidantes.

10.6 Produtos de decomposição perigosos

Óxidos de carbono, óxidos de potássio.

Secção 11: Informações toxicológicas

11.1 Informações sobre efeitos toxicológicos

Componentes		
Cloreto de amónio (20% A 30%)	12125-02-9	**Toxicidade aguda:** Ingestão/Oral-Rato LD50 • 1650 mg/kg; **Irritação:** Olho-Coelho • 100 mg • Irritação grave
Carbonato de potássio (1% A 5%)	584-08-7	**Toxicidade aguda:** Ingestão/Oral-Rato LD50 • 1870 mg/kg; **Toxicidade multidose:** Inalação-rato TCLo • 43 mg/m³ 17 semana(s); *Cardíaca*: **alterações no ECG não diagnósticas do supramencionado**; *Rins, uréter e bexiga*: **outras alterações na composição da urina**; *Nutricionais e metabólicas grosseiras: alterações na química ou temperatura*:K ; **Mutagénio:** Síntese de ADN não programada • Ingestão/oral-rato • 504 g/kg 4 semana(s) — contínua

Propriedades do GHS	Classificação
Toxicidade aguda	**UE/CLP**•Dados em falta **GHS da ONU 3**•Toxicidade aguda — oral 5 — ATEmix (oral) = 4795 mg/kg **OSHA HCS 2012**•Dados em falta
Corrosão/irritação cutânea	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Lesão/irritação ocular grave	**UE/CLP**•Irritação ocular 2 **GHS da ONU 3**•Irritação ocular 2 **OSHA HCS 2012**•Irritação ocular 2
Sensibilização da pele	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Sensibilização respiratória	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Perigo de aspiração	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Carcinogenicidade	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Mutagenicidade de células germinativas	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
Toxicidade da reprodução	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-SE	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta
STOT-RE	**UE/CLP**•Dados em falta **GHS da ONU 3**•Dados em falta **OSHA HCS 2012**•Dados em falta

Potenciais efeitos na saúde

Inalação
Agudo (Imediato) Sem dados disponíveis
Crónico (Retardado) Sem dados disponíveis
Pele
Agudo (Imediato) Sem dados disponíveis
Crónico (Retardado) Sem dados disponíveis
Olhos
Agudo (Imediato) Provoca irritação ocular grave.
Crónico (Retardado) Sem dados disponíveis
Ingestão
Agudo (Imediato) Pode ser nocivo em caso de ingestão.
Crónico (Retardado) Sem dados disponíveis

Chave para abreviaturas
LD = Dose letal
TC = Concentração tóxica

Secção 12: Informações ecológicas

12.1 Toxicidade

	CAS	
Xpert Urine Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit	NDA	**Toxicidade aquática-peixes:** 4 dia(s) LC50 *Peixe-rei-verde* 0,14 mg/l Comentários: Cloreto de amónio (12125-02-9) 30 dia(s) NOEC *Peixe-gato pontuado* 0,006 mg/l Comentários: Cloreto de amónio (12125-02-9) **Toxicidade aquática-crustáceos:** 2 dia(s) EC50 *Ostracod* 0,075-0,126 mg/l Comentários: Cloreto de amónio (12125-02-9) 21 dia(s) NOEC *Pulga de água* 0,05 mg/l Comentários: Cloreto de amónio (12125-02-9) **Toxicidade aquática-algas e outra(s) planta(s) aquática(s):** 3 dia(s) EC50 *Algas colar de Neptuno* 0,04-0,1 mg/l Comentários: Cloreto de amónio (12125-02-9)

Tóxico para a vida aquática. Tóxico para a vida aquática com efeitos duradouros.

12.2 Persistência e degradabilidade

Dados dos materiais em falta.

12.3 Potencial bioacumulativo

Dados dos materiais em falta.

12.4 Mobilidade no solo

Dados dos materiais em falta.

12.5 Resultados de avaliação PBT e vPvB

Não foi feita a avaliação PBT e vPvB.

12.6 Outros efeitos adversos

Não foram encontrados estudos.

Secção 13: Considerações sobre a eliminação

13.1 Métodos de tratamento de dejetos

Produto residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

Embalagem residual Eliminar o conteúdo e/ou recipiente de acordo com a regulamentação local, regional, nacional e/ou internacional.

13.2 Outras informações

As amostras biológicas, incluindo cartuchos usados, devem ser tratadas como potenciais fontes de transmissão de agentes infeciosos. Consultar os técnicos responsáveis pelos resíduos ambientais da sua instituição relativamente à eliminação correta de cartuchos usados e reagentes não utilizados. Este material pode apresentar características de resíduos perigosos segundo a Lei de Recuperação e Conservação de Recursos (RCRA) da Agência de Proteção Ambiental (EPA), que exijam requisitos de eliminação específicos. Verificar as regulamentações estaduais e locais, uma vez que poderão diferir das regulamentações federais de eliminação de resíduos. As instituições fora dos EUA devem verificar os requisitos relativos à eliminação de resíduos perigosos dos respetivos países.

Secção 14: Informações sobre transporte

	14.1 Número na ONU	14.2 Nome de transporte adequado (ONU)	14.3 Classe(s) de transporte de risco	14.4 Grupo de embalagem	14.5 Perigos ambientais
DOT	Não aplicável	Não regulamentado	Não aplicável	Não aplicável	NDA
TDG	UN3082	SUBSTÂNCIA AMBIENTALMENTE PERIGOSA, LÍQUIDO, N.O.S. (cloreto de amónio)	9	III	NDA
IMO/IMDG	UN3082	SUBSTÂNCIA AMBIENTALMENTE PERIGOSA, LÍQUIDO, N.O.S. (cloreto de amónio)	9	III	NDA
IATA/ICAO	UN3082	SUBSTÂNCIA AMBIENTALMENTE PERIGOSA, LÍQUIDO, N.O.S. (cloreto de amónio)	9	III	NDA

14.6 Precauções especiais para o utilizador

Nenhuma especificada.

14.7 Transporte a granel segundo o Anexo II de MARPOL 73/78 e o código do IBC

Dados em falta.

Secção 15: Informações regulamentares

15.1 Regulamentos/legislação de segurança, saúde e ambientais, específicos da substância ou mistura

Classificações de Risco SARA Agudo

Inventário						
Componente	**CAS**	**DSL (Canadá)**	**NDSL (Canadá)**	**EINECS (UE)**	**ELNICS (UE)**	**TSCA**
Cloreto de amónio	12125-02-9	Sim	Não	Sim	Não	Sim
Carbonato de potássio	584-08-7	Sim	Não	Sim	Não	Sim

Ficha de dados de segurança

Data de entrada em vigor: Fevereiro de 2020
Data de substituição: Julho de 2016

Xpert Urine Specimen Collection Kit
Xpert CT/NG Urine Specimen Collection Kit

Canadá

Trabalho

Canadá - WHMIS - Classificação de Substâncias

•Carbonato de potássio	584-08-7	D2B, E
•Cloreto de amónio	12125-02-9	D2B

Canadá - WHMIS - Lista de Divulgação de Ingredientes

•Carbonato de potássio	584-08-7	1%
•Cloreto de amónio	12125-02-9	1%

Ambiente

Canadá - CEPA - Lista de Substâncias Prioritárias

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

Estados Unidos da América

Trabalho

E.U.A. - OSHA - Gestão de Segurança do Processo - Produtos Químicos Altamente Perigosos

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

E.U.A. - OSHA - Químicos com Regulamentação Específica

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

Ambiente

E.U.A. - CAA (Lei do Ar Puro) - 1990 Poluentes Atmosféricos Perigosos

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

E.U.A. - CERCLA/SARA - Substâncias Perigosas e Respetivas Quantidades de Comunicação Obrigatória

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	5000 lb RQ final; 2270 kg RQ final

E.U.A. - CERCLA/SARA - Radionuclídeos e Respetivas Quantidades de Comunicação Obrigatória

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

E.U.A. - CERCLA/SARA - Secção 302 Quantidades de Comunicação Obrigatória de Substâncias Extremamente Perigosas da EPCRA

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

E.U.A. - CERCLA/SARA - Secção 302 Planeamento de Quantidades Limite de Substâncias Extremamente Perigosas

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

E.U.A. - CERCLA/SARA - Secção 313 - Relatório de Emissão

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

E.U.A. - CERCLA/SARA - Secção 313 - Listagem de Produtos Químicos PBT

•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

Estados Unidos da América - Califórnia

Ambiente

E.U.A. - Califórnia - Proposta 65 - Lista de Substâncias Cancerígenas		
•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para o Desenvolvimento		
•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado
E.U.A. - Califórnia - Proposta 65 - Níveis Máximos de Dose Permitidos (MADL)		
•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado
E.U.A. - Califórnia - Proposta 65 - Sem Níveis de Risco Significativos (NSRL)		
•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Mulheres		
•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado
E.U.A. - Califórnia - Proposta 65 - Toxicidade para a Reprodução - Homens		
•Carbonato de potássio	584-08-7	Não listado
•Cloreto de amónio	12125-02-9	Não listado

15.2 Avaliação da segurança química

Não foi efetuada qualquer Avaliação da Segurança Química.

Secção 16: Outras informações

Frases relevantes (código e texto)

H302 — Nocivo por ingestão

Renúncia/ Declaração de responsabilidade

A informação supramencionada baseia-se em dados que nos foram disponibilizados e é tida como correta. Dado que a informação pode ser aplicada em condições fora do nosso controlo e com as quais podemos não estar familiarizados, não assumimos qualquer responsabilidade pelo resultado da sua utilização, e todas as pessoas que a recebam têm de determinar individualmente os efeitos, as propriedades, as proteções e os procedimentos de eliminação que se aplicam às suas condições particulares. Não se assume qualquer representação ou garantia, implícita ou explicitamente (incluindo garantia de adequação ou comerciabilidade para uma finalidade específica) em relação aos materiais, à exatidão desta informação, aos resultados obtidos decorrentes da sua utilização ou a perigos relacionados com a utilização deste material. Deve-se ter cuidado no manuseamento e utilização deste material. A informação anterior é disponibilizada de boa-fé e é tida como exata. À data de emissão, fornecemos toda a informação relevante para um manuseamento previsível do material. No entanto, caso ocorra um incidente adverso associado a este produto, esta ficha de dados de segurança não substitui, nem se pretende que substitua, a consulta de um profissional com formação adequada. Fornecer renúncia.

Chave para abreviaturas
NDA = Nenhuns Dados Disponíveis

Паспорт безопасности материала
Дата вступления в силу: февраль, 2020 г.
Отменяет версию документа за: июль, 2016 г.

Набор для сбора образца мочи Xpert
набор для сбора образца мочи Xpert CT/NG

Раздел 1: Общие сведения о веществе/смеси и производителе

1.1 Идентификатор продукта

Наименование продукта	**Набор для сбора образца мочи Xpert, набор для сбора образца мочи Xpert CT/NG**
Код продукта	CT/NGURINE-50; URINE/A-50

1.2 Рекомендованные и не рекомендованные способы применения вещества или смеси

Рекомендованные способы применения	Для использования в лабораторных условиях

1.3 Сведения об организации, предоставившей паспорт безопасности материала

Производитель	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 United States (США) www.cepheid.com США: techsupport@cepheid.com
Телефон (общий)	1 (888) 838-3222 - США, дополнит. 2
Телефон (общий)	1 (408) 541-4191 - За пределами США
Поставщик	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden (Швеция) www.cepheidinternational.com ЕС: support@cepheideurope.com
Телефон (общий)	+33 563 825 319

1.4 Телефон для экстренной связи

Производитель	+ 1 (800) 535-5053 - INFOTRAC - круглосуточный телефон экстренного вызова
Производитель	+ 1 (352) 323-3500- За пределами США

Cepheid

Паспорт безопасности материала

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Раздел 2: Идентификация опасности

ЕС/ЕЭС

Согласно: Регламенту ЕК (ЕС) № 1272/2008 (CLP)/REACH 1907/2006 [с поправками, внесенными постановлением 453/2010]

2.1 Классификация вещества или смеси

Регламент CLP

Следующий паспорт безопасности материала действителен только для готового продукта, используемого в лабораторных условиях. Содержит жидкие компоненты, некоторые из которых лиофилизированы, а также реактивы, содержащиеся в картридже и во флаконе Nalgene. Все реактивы представляют собой прозрачные бесцветные жидкости. Исключения в отношении разглашения информации о некоторых компонентах предусмотрены статьей 1(5)(d) Регламента CLP и разделом 29 Свода федеральных правил (CFR) США, ст. 1910.1200(g)(2)(i)(C)(1)&(2).
Раздражение глаз, 2 - H319

2.2 Элементы маркировки

Регламент CLP

ВНИМАНИЕ!

Указания на опасность

H319 - Вызывает серьезное раздражение глаз

Меры предосторожности

Профилактика

P264 - После использования тщательно вымыть.
P280 - Пользуйтесь защитными перчатками, защитной одеждой, средствами защиты глаз/лица.

Реагирование

P305+P351+P338 - ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание.
P337+P313 - Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

2.3 Другие факторы опасности

Регламент CLP

Согласно Регламенту ЕК № 1272/2008 (CLP) этот материал считается опасным.

СГС ООН, редакция 3

Согласно: Согласованная на глобальном уровне система классификации опасности и маркировки химической продукции (СГС) ООН:
третья пересмотренная редакция

2.1 Классификация вещества или смеси

СГС ООН

Острая токсичность, перорально, 5
Раздражение глаз, 2
Опасность для водной среды, острая, 1
Опасность для водной среды, при хроническом воздействии, 1

2.2 Элементы маркировки

СГС ООН

ВНИМАНИЕ!

Указания на опасность	Может быть вредно при проглатывании Вызывает серьезное раздражение глаз Очень токсично для водных организмов Очень токсично для водных организмов с долгосрочными последствиями
Меры предосторожности	
Профилактика	После использования тщательно вымыть. Избегайте попадания в окружающую среду. Пользуйтесь защитными перчатками, защитной одеждой, средствами защиты глаз/лица.
Реагирование	ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью. При плохом самочувствии обратиться в ТОКСИКОЛОГИЧЕСКИЙ ЦЕНТР или к врачу-специалисту/терапевту. Ликвидировать разлив.
Хранение/удаление в отходы	Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

2.3 Другие факторы опасности

СГС ООН	В соответствии с Согласованной на глобальном уровне системой классификации опасности и маркировки химической продукции (СГС) данный продукт считается опасным.

США
Согласно: OSHA 29 CFR 1910.1200 HCS

2.1 Классификация вещества или смеси

OSHA HCS 2012	Раздражение глаз, 2

2.2 Элементы маркировки

OSHA HCS 2012

ВНИМАНИЕ!

Указания на опасность	Вызывает серьезное раздражение глаз
Меры предосторожности	
Профилактика	После использования тщательно вымыть. Пользуйтесь защитными перчатками, защитной одеждой, средствами защиты глаз/лица.
Реагирование	ДЕЙСТВИЯ ПРИ ПОПАДАНИИ В ГЛАЗА. Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь и если это легко сделать. Продолжить промывание. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

2.3 Другие факторы опасности

OSHA HCS 2012

Согласно государственным нормам США (документ 29 CFR 1910.1200 - Стандарт-требование об оповещении об опасности) этот продукт считается опасным.

Канада
Согласно: WHMIS

2.1 Классификация вещества или смеси

WHMIS

Другие токсические эффекты, D2B

2.2 Элементы маркировки

WHMIS

Другие токсические эффекты, D2B

2.3 Другие факторы опасности

WHMIS

В Канаде указанное выше вещество согласно требованиям Информационной системы по опасным материалам на рабочих местах (WHMIS) считается опасным.

2.4 Дополнительная информация

Все остальные реактивы, гранулы и прочие составляющие представлены в смеси в концентрациях менее 1% или не считаются опасными согласно Стандартам-требованиям США об оповещении об опасности (29 CFR 1910.1200), директивам ЕС в отношении классификации и маркировки веществ и смесей и Согласованной на глобальном уровне системе классификации опасности и маркировки химической продукции (СГС).

Паспорт безопасности материала
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набор для сбора образца мочи Xpert CT/NG

Раздел 3: Состав/информация о компонентах

3.1 Вещества

Материал не отвечает критериям классификации, применяемым к веществам.

3.2 Смеси

Состав					
Химическое наименование	**Идентификаторы**	**%**	**LD50/LC50**	**Классификация в соответствии с нормами/постановлениями**	**Комментарии**
Хлорид аммония	**CAS:** 12125-02-9 **Номер EC:** 235-186-4 **Индекс EU:** 017-014-00-8	ОТ 20% ДО 30%	прием внутрь/перорально-крыса LD50 • 1650 мг/кг	**EU CLP:** приложение VI, таблица 3.1: острая токсичность 4 *, H302; раздражение глаз 2, H319 **СГС ООН, редакция 3:** острая токсичность 4 (перорально); раздражение глаз 2; острая токсичность для водной среды 1; токсично для водной среды при хроническом воздействии 1 **OSHA HCS 2012:** острая токсичность 4 (перорально); раздражение глаз 2	Нет данных
Карбонат калия	**CAS:**584-08-7 **Номер EC:** 209-529-3	ОТ 1% ДО 5%	прием внутрь/перорально-крыса LD50 • 1870 мг/кг	**EU CLP:** острая токсичность 4, H302 **СГС ООН, редакция 3:** острая токсичность 4 (перорально); раздражение глаз 2B **OSHA HCS 2012:** острая токсичность 4 (перорально); раздражение глаз 2B	Нет данных

См. раздел 16 с полным текстом указаний на опасность.

Раздел 4: Первая медицинская помощь

4.1 Описание мер первой медицинской помощи

Вдыхание Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. Вынести пострадавшего на свежий воздух. При затрудненном дыхании дать кислород. При вдыхании вещества не применять искусственное дыхание рот-в-рот. Выполнить искусственное дыхание с помощью карманной маски с клапаном одностороннего действия или другого подходящего медицинского устройства. При остановке дыхания обеспечить искусственное дыхание/ИВЛ.

Кожа Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При незначительном контакте с кожей избегайте распространения материала на незатронутые участки. В случае контакта вещества с кожей незамедлительно промыть пораженный участок проточной водой в течение не менее чем 20 минут. Снять и изолировать загрязненную одежду.

Глаза Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. В случае попадания вещества незамедлительно промыть глаза проточной водой в течение не менее чем 20 минут. Если раздражение глаз не проходит: обратиться за медицинской консультацией/помощью.

Проглатывание	Ожидается, что первая помощь не потребуется, если материал используется в обычных условиях и с соблюдением рекомендаций. При проглатывании прополоскать рот водой (только если человек находится в сознании). НЕ вызывать рвоту. Не применять искусственное дыхание рот-в-рот при проглатывании вещества. При проглатывании материала сразу же обратиться к врачу.

4.2 Наиболее важные симптомы и последствия, проявляющиеся немедленно и с задержкой

См. раздел 11, «Токсикологическая информация».

4.3 Признаки необходимости неотложной медицинской помощи и специального лечения

Примечания для врача	Лечение основывать на наблюдаемых симптомах. Учитывать возможность одновременного чрезмерного воздействия на пациента и других веществ, помимо данного продукта.

Раздел 5: Меры противопожарной безопасности

5.1 Средства пожаротушения

Подходящие средства пожаротушения	КРУПНЫЕ ПОЖАРЫ. Сухое химическое огнетушащее средство, углекислый газ (CO2), спиртоустойчивые пенообразователи, распыленная вода. НЕБОЛЬШИЕ ПОЖАРЫ. Сухое химическое огнетушащее средство, углекислый газ (CO2), распыленная вода.
Непригодные средства пожаротушения	Данные отсутствуют

5.2 Особые аспекты опасности вещества или смеси

Особая огне- и взрывоопасность	Возможно выделение токсичных испарений: оксиды углерода, оксиды азота.
Опасные продукты горения	Данные отсутствуют

5.3 Рекомендации по пожаротушению

Защитная одежда пожарных для тушения пожаров в зданиях обеспечивает ограниченную защиту ТОЛЬКО в условиях пожара; она не является эффективным средством защиты при разливах с возможным непосредственным контактом с веществами.
Носить одежду для химической защиты, рекомендованную производителем. Она может быть малоэффективна или неэффективна в качестве тепловой защиты.
Использовать автономные дыхательные аппараты, работающие в режиме положительного давления.
НЕБОЛЬШИЕ ПОЖАРЫ. Уберите контейнеры из зоны пожара, если можете сделать это без риска.

Раздел 6: Меры по предотвращению и ликвидации последствий случайного выброса материала

6.1 Меры по обеспечению личной безопасности, средства защиты и действия в чрезвычайной ситуации

Меры по обеспечению личной безопасности	В случае разбития картриджа актуальны указанные меры по обеспечению личной безопасности. Используйте соответствующую защитную одежду. Не ходите по разлитому/просыпанному материалу. Не прикасайтесь к поврежденным контейнерам или разлитому/просыпанному материалу, если нет соответствующей защитной одежды. Проветрите закрытые помещения.
Действия в чрезвычайных ситуациях	Ожидается, что экстренные меры не потребуются, если материал используется в обычных условиях и с соблюдением рекомендаций.

6.2 Меры по защите окружающей среды

Не допускать попадания в водотоки, канализацию, подвалы и замкнутые пространства.

6.3 Методы и средства локализации и очистки

Меры и средства локализации и очистки	При небольших разливах используйте перчатки. Для сбора вещества используйте бумажные полотенца. Не сливать пролитые вещества в канализацию.

6.4 Ссылки на другие разделы

См. раздел 8, «Меры контроля воздействия и средства индивидуальной защиты», и раздел 13, «Условия удаления в отходы».

Раздел 7: Правила обращения и хранения

7.1 Меры предосторожности при обращении с продуктом

Обращение	Особое обращение не требуется. В случае разбития картриджа избегайте контакта с разлившимися реактивами. Избегать контакта с кожей и глазами.

7.2 Условия безопасного хранения и учет факторов несовместимости

Место хранения	Хранить согласно указаниям на упаковке. Хранить в плотно закрытом контейнере/упаковке в прохладном, хорошо проветриваемом месте. Хранить вдали от несовместимых материалов.

7.3 Особые способы применения

См. раздел 1.2, «Рекомендованные способы применения».

Раздел 8: Меры контроля воздействия и средства индивидуальной защиты

8.1 Контрольные параметры

Предельно допустимые концентрации/рекомендации			
	Результат	**ACGIH**	**NIOSH**
Хлорид аммония (12125-02-9)	STEL	20 мг/м3 STEL (пары)	20 мг/м3 STEL (пары)
	TWA	10 мг/м3 TWA (пары)	10 мг/м3 TWA (пары)

8.2 Меры контроля воздействия

Инженерно-технические мероприятия/средства контроля
Следует обеспечить хорошую общую вентиляцию. Интенсивность вентиляции должна соответствовать условиям хранения/использования. Если возможно, используйте изолированное рабочее пространство, местную вытяжную вентиляцию и прочие инженерно-технические средства для сдерживания концентрации вещества в воздухе на уровне ниже ПДК. Если ПДК не установлены, поддерживайте приемлемые концентрации вещества в воздухе.

Индивидуальные средства защиты

Защита органов дыхания
Соблюдайте рекомендации по использованию респираторов Управления охраны труда (OSHA) США, изложенные в документе 29 CFR 1910.134, или Европейского стандарта EN 149. При превышении ПДК или обнаружении признаков поражения используйте респираторы, одобренные Национальным институтом по безопасности и гигиене труда (NIOSH) США, Управлением по безопасности и охране труда в добывающей промышленности (MSHA) США или Европейским стандартом EN 149.

Защита глаз/лица
Носите очки химической защиты.

Защита кожных покровов/тела
При работе в лаборатории для сведения к минимуму риска контакта с кожей используйте перчатки и халат.

Защита окружающей среды
Соблюдайте общие правила работы на объекте и удаления отходов.

Сокращения
ACGIH = Американская конференция правительственных специалистов по гигиене труда в промышленности (American Conference of Governmental and Industrial Hygiene).
NIOSH = Национальный институт по безопасности и гигиене труда, США (National Institute of Occupational Safety and Health).
OSHA = Управление охраны труда, США (Occupational Safety and Health Administration).
STEL = пределы кратковременного воздействия, основанные на 15-минутном периоде.
TWA = Средневзвешенная во времени концентрация, вычисляемая на основании воздействия в течение 8 часов в день, 40 часов в неделю.

Раздел 9: Физические и химические свойства

9.1 Информация о физических и химических свойствах

Описание материала			
Физическая форма	Жидкость	Внешний вид/описание	Реактивы представляют собой прозрачные бесцветные жидкости без запаха, в основном буферизованные в водных растворах.
Цвет	Прозрачная	Запах	Без запаха
Порог ощущения запаха	Данные отсутствуют		
Общие свойства			
Точка кипения	100 °C (212 °F)	Температура плавления/замерзания	0 °C (32 °F)
Температура разложения	Данные отсутствуют	pH	от 8 до 8,3 (твердые вещества и прочие жидкие реактивы)
Удельный вес/относительная плотность	Данные отсутствуют	Растворимость в воде	Данные отсутствуют
Вязкость	Данные отсутствуют	Взрывчатые свойства	Данные отсутствуют
Окислительные свойства:	Данные отсутствуют		
Летучесть			
Давление паров	Данные отсутствуют	Плотность паров	Данные отсутствуют
Интенсивность испарения	Данные отсутствуют		
Воспламеняемость			
Температура вспышки	Данные отсутствуют	ВКПВ (верхний предел взрываемости)	Данные отсутствуют
НПВ (нижний предел взрываемости)	Данные отсутствуют	Самовоспламенение	Данные отсутствуют
Воспламеняемость (в твердом, газообразном состоянии)	Данные отсутствуют		
В отношении окружающей среды			
Коэффициент распределения октанол/вода	Данные отсутствуют		

9.2 Дополнительная информация

Дополнительные физические и химические свойства не обнаружены.

Раздел 10: Стабильность и реакционная способность

10.1 Реакционная способность

В нормальных условиях использования опасные реакции неизвестны.

10.2 Химическая стабильность

Стабильно

10.3 Вероятность опасных реакций

Опасная полимеризация не происходит.

10.4 Условия, которых следует избегать

Нагрев, влажность (факторы, влияющие на качество продукта)

10.5 Несовместимые материалы

Кислоты, окислители.

10.6 Опасные продукты разложения

Оксиды углерода, оксиды калия.

Раздел 11: Токсикологическая информация

11.1 Информация о токсикологических последствиях

		Компоненты
Хлорид аммония (ОТ 20% ДО 30%)	12125-02-9	**Острая токсичность:** прием внутрь/перорально-крыса LD50 • 1650 мг/кг **Раздражение:** глаза-кролик • 100 мг • сильное раздражение
Карбонат калия (ОТ 1% ДО 5%)	584-08-7	**Острая токсичность:** прием внутрь/перорально-крыса LD50 • 1870 мг/кг **Токсичность при неоднократном введении:** вдыхание-крыса TCLo • 43 мг/м³ 17 недель; *сердце*: **изменения на ЭКГ, не характерные для перечисленного выше**; *почки, мочеточники, мочевой пузырь*: **другие изменения состава мочи**; *питание и общий метаболизм: изменения биохимических показателей или температуры*: **K (калий)**; **Мутаген:** незапланированный синтез ДНК • прием внутрь/перорально-крыса • 504 г/кг 4 недели-непрерывный

Свойства (СГС)	**Классификация**
Острая токсичность	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Острая токсичность - перорально - категория 5 - расчетная оценка острой токсичности ATEmix (пероральное введение) = 4795 мг/кг **OSHA HCS 2012** • Данные отсутствуют
Разъедающее/раздражающее воздействие на кожу	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Серьезное повреждение/раздражение глаз	**EU/CLP** • Раздражение глаз, категория 2 **СГС ООН 3** • Раздражение глаз, категория 2 **OSHA HCS 2012** • Раздражение глаз, категория 2
Сенсибилизация кожи	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Сенсибилизация органов дыхания	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Опасность при аспирации	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Канцерогенность	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Мутагенность для зародышевых клеток	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Токсическое действие на репродуктивную функцию	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют

Свойства (СГС)	Классификация
Органоспецифическая токсичность при однократном воздействии (STOT-SE)	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют
Органоспецифическая токсичность при многократном воздействии (STOT-RE)	**EU/CLP** • Данные отсутствуют **СГС ООН 3** • Данные отсутствуют **OSHA HCS 2012** • Данные отсутствуют

Возможные последствия для здоровья

Вдыхание
Острые последствия Данные отсутствуют
Хронические последствия Данные отсутствуют

Кожа
Острые последствия Данные отсутствуют
Хронические последствия Данные отсутствуют

Глаза
Острые последствия Вызывает серьезное раздражение глаз.
Хронические последствия Данные отсутствуют

Проглатывание
Остро выраженные последствия Может быть вредно при проглатывании.
Хронические последствия Данные отсутствуют

Сокращения
LD = Летальная доза
TC = токсическая концентрация

Раздел 12: Информация о воздействии на окружающую среду

12.1 Токсичность

	CAS	
Набор для сбора образца мочи Xpert, набор для сбора образца мочи Xpert CT/NG	Нет данных	**Токсичность для водных организмов-рыбы:** 4 дня LC50 *атлантическая менидия* 0,14 мг/л Комментарии: Хлорид аммония (12125-02-9) 30 дней NOEC *американский сомик* 0,006 мг/л Комментарии: Хлорид аммония (12125-02-9) **Токсичность для водных организмов-ракообразные:** 2 дня EC50 *ракушковые ракообразные* 0,075-0,126 мг/л Комментарии: Хлорид аммония (12125-02-9) 21 день NOEC *дафния* 0,05 мг/л Комментарии: Хлорид аммония (12125-02-9) **Токсичность для водных организмов-водоросли и другие водные растения:** 3 дня EC50 *хормозира Банкса* 0,04-0,1 мг/л Комментарии: Хлорид аммония (12125-02-9)

Токсично для водных организмов. Токсично для водных организмов с долгосрочными последствиями.

12.2 Устойчивость и способность к разложению

Данные о материале отсутствуют.

12.3 Способность к биоаккумуляции

Данные о материале отсутствуют.

12.4 Подвижность в почве

Данные о материале отсутствуют.

12.5 Результаты оценки соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества»

Оценка соответствия признакам «устойчивого биоаккумулятивного токсического вещества» и «очень устойчивого биоаккумулятивного вещества» не производилась.

12.6 Другие неблагоприятные последствия

Исследования не проводились.

Раздел 13: Условия удаления в отходы

13.1 Методы переработки отходов

Отходы продукта Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

Отходы упаковки Удаление в отходы тары и/или содержимого должно осуществляться в соответствии с местными, региональными, государственными и/или международными нормами.

13.2 Дополнительная информация

К биологическим образцам, включая использованные картриджи, следует относиться как материалам, способным служить источником инфекционного заражения. По вопросам надлежащего удаления в отходы использованных картриджей и неиспользованных реактивов проконсультируйтесь с лицами, ответственными за обращение с отходами в вашей организации. Данный материал может иметь характеристики опасных отходов с особыми требованиями к удалению отходов, предусмотренные агентством EPA согласно Федеральному закону об охране и восстановлении ресурсов (RCRA) США. Ознакомьтесь с местными нормами, так как они могут отличаться от федеральных норм. Организации за пределами США должны ознакомиться с нормами обращения с опасными отходами, принятыми в соответствующих странах.

Раздел 14: Информация о транспортировке

	14.1 Номер ООН	14.2 Отгрузочное наименование ООН	14.3 Класс(-ы) опасности при транспортировке	14.4 Группа упаковки	14.5 Опасность для окружающей среды
DOT	Неприменимо	Не регулируется	Неприменимо	Неприменимо	Нет данных
TDG	UN3082	ВЕЩЕСТВО ЖИДКОЕ, ОПАСНОЕ ДЛЯ ОКРУЖАЮЩЕЙ СРЕДЫ, Н.У.К. (хлорид аммония)	9	III	Нет данных
IMO/IMDG	UN3082	ВЕЩЕСТВО ЖИДКОЕ, ОПАСНОЕ ДЛЯ ОКРУЖАЮЩЕЙ СРЕДЫ, Н.У.К. (хлорид аммония)	9	III	Нет данных
IATA/ICAO	UN3082	ВЕЩЕСТВО ЖИДКОЕ, ОПАСНОЕ ДЛЯ ОКРУЖАЮЩЕЙ СРЕДЫ, Н.У.К. (хлорид аммония)	9	III	Нет данных

14.6 Специальные меры предосторожности для пользователей

Не указаны.

14.7 Бестарная транспортировка в соответствии с Приложением II MARPOL 73/78 и Кодексом IBC

Данные отсутствуют.

Раздел 15: Нормативная информация

15.1 Правовые акты в сфере безопасности, защиты здоровья и окружающей среды/особые правовые акты, применимые к веществу или смеси

Класс опасности (SARA) Острая

Реестр						
Компонент	**CAS**	**Канада, DSL**	**Канада, NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
Хлорид аммония	12125-02-9	Да	Нет	Да	Нет	Да
Карбонат калия	584-08-7	Да	Нет	Да	Нет	Да

Канада

Охрана труда

Канада - Информационная система по опасным материалам на рабочих местах (WHMIS) - Классификация веществ

•Карбонат калия	584-08-7	D2B, E
•Хлорид аммония	12125-02-9	D2B

Канада - WHMIS - Перечень ингредиентов, информация о которых подлежит раскрытию

•Карбонат калия	584-08-7	1%
•Хлорид аммония	12125-02-9	1%

Окружающая среда

Канада - Закон Канады об охране окружающей среды (CEPA) - Список приоритетных веществ

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

Паспорт безопасности материала

Дата вступления в силу: февраль, 2020 г.
Отменяет версию документа за: июль, 2016 г.

Набор для сбора образца мочи Xpert
набор для сбора образца мочи Xpert CT/NG

United States (США)

Охрана труда

США - Управление охраны труда (OSHA) - Обеспечение безопасности производственного процесса - Высокоопасные химические вещества

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - OSHA - Особо контролируемые химические вещества

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

Окружающая среда

США - Закон о чистом воздухе (CAA), 1990 - Опасные загрязняющие воздух вещества

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - Акт о комплексном реагировании, компенсации и ответственности за ущерб окружающей среде (CERCLA)/Закон об улучшении финансирования и перераспределении полномочий (SARA) - Опасные вещества и их подотчетные количества

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	5000 фунтов, заключительное ПК; 2270 кг, заключительное ПК

США - CERCLA/SARA - Радионуклиды и их подотчетные количества

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - CERCLA/SARA - Раздел 302. Чрезвычайно опасные вещества. Закон о планировании действий при чрезвычайных ситуациях и праве общества на информацию (EPCRA) - подотчетные количества

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - CERCLA/SARA - Раздел 302. Чрезвычайно опасные вещества. Пороговые запланированные количества (TPQ)

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - CERCLA/SARA - Раздел 313. Оповещение о выбросах

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - CERCLA/SARA - Раздел 313. Список устойчивых биоаккумулятивных токсических веществ

•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

США - Калифорния

Окружающая среда

США - Калифорния - Предложение 65 - Список канцерогенов		
•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится
США - Калифорния - Предложение 65 - Эмбрифетотоксичность		
•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится
США - Калифорния - Предложение 65 - Предельно допустимые дозы (MADL)		
•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится
США - Калифорния - Предложение 65 - Концентрации веществ, не несущие значимого риска (NSRL)		
•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится
США - Калифорния - Предложение 65 - Репродуктивная токсичность - Влияние на женский организм		
•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится
США - Калифорния - Предложение 65 - Репродуктивная токсичность - Влияние на мужской организм		
•Карбонат калия	584-08-7	Не числится
•Хлорид аммония	12125-02-9	Не числится

15.2 Оценка химической безопасности

Оценка химической безопасности не проводилась.

Раздел 16: Дополнительная информация

Соответствующие фразы (код и текст)

H302 - Вредно при проглатывании

Отказ от ответственности/ ограничение ответственности

Представленные выше сведения основаны на доступных нам данных и считаются верными. В связи с тем, что представленная информация может быть использована в независящих от нас и неизвестных нам условиях, мы не несем ответственность за последствия ее использования, а все лица, получающие эту информацию, должны самостоятельно принимать решения относительно последствий применения, свойств, средств защиты и способов удаления в отходы в соответствии с конкретными условиями применения. Мы не заявляем, не даем каких-либо гарантий и поручительств, явных или подразумеваемых (включая гарантии пригодности или товарной пригодности для конкретной цели), в отношении материалов и точности информации, полученных при их использовании результатов, а также опасностей, связанных с использованием данного материала. При обращении с материалом и его использовании следует проявлять осторожность. Представленная выше информация передана добросовестно с уверенностью в ее точности. Мы предоставляем всю информацию, касающуюся предполагаемого использования материала, по состоянию на момент публикации. Однако в случае нежелательных последствий, связанных с данным продуктом, настоящий паспорт безопасности материала не является и не может являться заменой консультации с соответствующим специалистом. Предоставить отказ от ответственности.

安全数据表

生效日期：2020 年 2 月
更换日期：2016 年 7 月

Xpert Urine Specimen Collection Kit（Xpert 尿液样本采集工具包）
Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）

第 1 章：物质/混合物标识和公司/企业标识

1.1 产品识别

产品名称 Xpert Urine Specimen Collection Kit（Xpert 尿液样本采集工具包）、Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）

产品代码 CT/NGURINE-50; URINE/A-50

1.2 物质或混合物的有关确定用途及不建议用途

有关确定用途 实验室使用

1.3 供应商安全数据表详情

制造商 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US：techsupport@cepheid.com

电话（通用） 1 (888) 838-3222 - 美国（选 2）

电话（通用） 1 (408) 541-4191 - 美国境外

供应商 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
欧盟：support@cepheideurope.com

电话（通用） +33 563 825 319

1.4 紧急电话号码

制造商 + 1 (800) 535-5053 - INFOTRAC - 24 小时紧急电话

制造商 + 1 (352) 323-3500- 美国境外

安全数据表

生效日期：2020 年 2 月
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Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）

第 2 章：危险标识

EU/EEC

根据：第 1272/2008 号规章（欧共体）(CLP)/REACH 1907/2006 [修订版 453/2010]

2.1 物质或混合物的分类

CLP

以下 SDS 仅适用于用于实验室的最终成品。它含有液体组分，其中一些呈冷冻干燥粉末状和制剂状，装于盒子和 Nalgene 瓶子中。所有制剂均为清澈、无色液体。
例外地披露某些组分信息的依据是 CLP Article 1(5)(d) 和 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2)。
眼刺激 2 - H319

2.2 标签元素

CLP

警告

危险声明 H319 - 导致严重的眼睛刺激

防范声明

预防 P264 - 处理之后要彻底清洗。
P280 - /防护服/护目装备/护面装备。

响应 P305+P351+P338 - 如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
P337+P313 - 如果眼睛刺激持续：获得医疗指导/就医治疗。

2.3 其他危险

CLP

根据欧共体 1272/2008 号规章（CLP），认为这种材料是危险材料。

UN GHS 修订版 3

根据：联合国 (UN) 全球化学品统一分类和标签制度 (GHS)：
第三次修订版

2.1 物质或混合物的分类

UN GHS

急性经口毒性 5
眼刺激 2
对水生环境急性危害 1
对水生环境慢性危害 1

安全数据表

生效日期：2020 年 2 月 *Xpert Urine Specimen Collection Kit（Xpert 尿液样本采集工具包）*

更换日期：2016 年 7 月 *Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）*

2.2 标签元素

UN GHS

警告

危险声明 如果吞入可能有害
导致严重的眼睛刺激
对水生生物非常有毒
对水生生物非常有毒，具有长期持续效应

防范声明

预防 处理之后要彻底清洗。
避免释放到环境中。
戴上防护手套/防护服/护目装备/护面装备。

响应 如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
如果眼睛刺激持续：获得医疗指导/就医治疗。
感到身体不适时，呼叫解毒中心或医生/医师。
收集泄漏物。

贮存/处置 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。

2.3 其他危险

UN GHS 根据全球统一分类和标签制度（GHS），认为该产品是危险品。

美国（US）

根据：OSHA 29 CFR 1910.1200 HCS

2.1 物质或混合物的分类

OSHA 的 HCS 2012 眼刺激 2

2.2 标签元素

OSHA 的 HCS 2012

警告

危险声明 导致严重的眼睛刺激

防范声明

预防 处理之后要彻底清洗。
戴上防护手套/防护服/护目装备/护面装备。

响应 如果进入眼睛：小心地用水冲洗若干分钟。如果佩戴隐形眼镜并且方便取下，则将其取下。继续冲洗。
如果眼睛刺激持续：获得医疗指导/就医治疗。

安全数据表

生效日期：2020 年 2 月 *Xpert Urine Specimen Collection Kit（Xpert 尿液样本采集工具包）*

更换日期：2016 年 7 月 *Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）*

2.3 其他危险

OSHA 的 HCS 2012 根据美国法规（29 CFR 1910.1200 - 危害通识标准），认为该产品是危险品。

加拿大

根据：WHMIS

2.1 物质或混合物的分类

WHMIS 其他毒性作用 - D2B

2.2 标签元素

WHMIS

其他毒性作用 - D2B

2.3 其他危险

WHMIS 在加拿大，根据工作场所有害材料信息系统（WHMIS），认为上述产品是危险品。

2.4 其他信息

所有其他制剂、颗粒和其他组分的浓度在混合物中均低于 1%，或者根据美国危害通识法规 (29 CFR 1910.1200)、欧盟物质或混合物分类与标签指令或全球物质或混合物分类与标签统一制度均不被认为是危险物质。

第 3 章：成分构成/信息

3.1 物质

该材料不符合某种物质的标准。

3.2 混合物

构成					
化学名称	**标识符**	**%**	**LD50/LC50**	**按规章/指令分类**	**注解**
氯化铵	**CAS:** 12125-02-9 **EC 编号：** 235-186-4 **EU 指数：** 017-014-00-8	20%至 30%	摄入/口服-大鼠 LD50 • 1650 mg/kg	**EU CLP：** 附录 VI, 表 3.1：急性毒性 4 *, H302；眼刺激 2, H319 **UN GHS 修订版 3:**急性毒性 4（口服）；眼刺激 2；水生急性 1；水生慢性 1 **OSHA HCS 2012:**急性毒性 4（口服）；眼刺激 2	NDA
碳酸钾	**CAS:**584-08-7 **EC 编号：** 209-529-3	1%至 5%	摄入/口服-大鼠 LD50 • 1870 mg/kg	**EU CLP：** 急性毒性 4, H302 **UN GHS 修订版 3：** 急性毒性 4（口服）；眼刺激 2B **OSHA HCS 2012:**急性毒性 4（口服）；眼刺激 2B	NDA

完整的危险声明全文，请参阅第 16 章。

安全数据表

生效日期：2020 年 2 月
更换日期：2016 年 7 月

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Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）

第 4 章：急救措施

4.1 急救措施描述

吸入

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。将受害者移至新鲜空气处。如果呼吸困难，就施用氧气。如果受害者吸入该物质，就不要使用口对口方法；借助配备单向阀或其他适当的呼吸医疗设备的袖珍面罩来给予人工呼吸。如果受害者没有呼吸，就给予人工呼吸。

皮肤

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。对于轻微的皮肤接触，避免使物质扩散到未受影响的皮肤上。在与物质接触的情况下，立即用流动的水冲洗眼睛至少 20 分钟。脱掉并隔离受污染的衣物。

眼睛

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。在与物质接触的情况下，立即用大量的水冲洗眼睛至少 20 分钟。如果眼睛刺激持续：获得医疗指导/就医治疗。

摄入

如果在一般条件下并且按照推荐方法使用材料，预计不必要进行急救。如果吞入，用水漱口（只有当伤员意识清楚时）。切勿催吐。如果受害者摄入该物质，请勿使用口对口人工呼吸法。如果摄入，立即就医。

4.2 急性及缓发的最重要症状及效应

请参阅第 11 章 - 毒物学信息。

4.3 任何需要立即就医及特别治疗的症候

对医生的注释

所有治疗措施均应根据所观察到的患者的痛苦症状和体征进行。应考虑可能发生过度暴露于非本品材料的可能性。

第 5 章：消防措施

5.1 灭火介质

适用的灭火介质

大火：化学干粉、二氧化碳、抗溶性泡沫或喷水。
小火：化学干粉，二氧化碳或喷水。

不适用的灭火介质

无可用数据

5.2 由物质或混合物产生的特殊危险

异常火灾和爆炸危险

可能会散发碳氧化物、氮氧化物有毒蒸气。

有害燃烧产物

无可用数据

5.3 供消防队员采纳的建议

建筑消防员的防护服只能在火情中提供有限的保护；它在可能与物质直接接触的溢出情况下无效。
穿上制造商专门推荐的化学防护服。它可能提供很少或根本没有提供热保护。
配戴正压自给式呼吸装置 (SCBA)。
小火：如果能够无风险地完成，就从火区移出容器。

第 6 章：意外释放措施

6.1 个人预防措施、防护装备和紧急程序

个人预防措施 万一盒子断裂，则适用于这些个人预防措施。穿戴适当的防护服。切勿踩踏泄漏物。除非穿着适当的防护服，否则不要触碰损坏的容器或溢出的物质。使封闭的地区通风。

应急程序 如果在一般条件下并且按照推荐的方法使用材料，预计不必要执行应急程序。

6.2 环保预防措施

防止进入水道、下水道、地下室或封闭区域。

6.3 用于遏制/净化的方法和材料

遏制/净化措施 对于少量撒漏，戴手套并用纸巾吸附撒漏物。切勿将撒漏的材料冲刷到排水管道中予以处置。

6.4 其他各章的参考

请参阅第 8 章 - 接触控制/个人防护以及第 13 章 - 处置注意事项。

第 7 章：操作和贮存

7.1 用于安全操作的预防措施

操作 无需任何特殊操作。如果盒子断裂，避免接触撒漏的制剂。避免接触皮肤和眼。

7.2 包括任何不相容性的安全贮存条件

贮存 按产品标签予以贮存。将容器/包装在阴凉、通风良好之处保持密闭。远离不相容材料。

7.3 特定最终用途

请参阅第 1.2 条 - 有关确定用途。

第 8 章：接触控制/个人防护

8.1 控制参数

接触限值/指南			
	结果	**ACGIH**	**NIOSH**
氯化铵 (12125-02-9)	STELs	20 mg/m3 STEL（烟雾）	20 mg/m3 STEL（烟雾）
	TWAs	10 mg/m3 TWA （烟雾）	10 mg/m3 TWA （烟雾）

8.2 接触控制

工程措施/控制 应当使用良好的通用通风设施。通风速率应当与环境相配。如果适用，使用工艺外罩、局部排气通风或其它工程控制设施，以保持空气中的浓度低于推荐的接触限值。如果尚未确定接触限值，就将空气中的浓度保持在可接受的水平。

个人防护装备

呼吸	遵守 29 CFR 1910.134 或欧洲标准 EN 149 中可见的 OSHA 呼吸器条例。如果超过接触限值 或出现症状，就使用 NIOSH/MSHA 或欧洲标准 EN 149 认可的呼吸器。
眼睛/面部	佩戴防化学剂飞溅护目镜。
皮肤/身体	在实验室环境中，至少戴手套、穿实验服，以将皮肤接触降到最低。
环境接触控制	遵守厂区管理和废物处置最佳规范。

略语表

ACGIH = 美国政府工业卫生学家会议
NIOSH = 国家职业安全和健康研究所
OSHA = 职业安全和健康管理局
STEL = 短期接触限值是基于 15 分钟接触量
TWA = 时间加权平均值根据 8 小时/天、40 小时/周的接触量来确定

第 9 章：物理性质和化学性质

9.1 有关物理性质和化学性质的信息

材料描述			
外形	液体	外形/描述	试剂是清澈、无色的液体，无味，主要 是没有臭味，主要是在水溶液中缓冲。
颜色	清澈	气味	无味
气味阈值	数据缺乏		
一般性质			
沸点	100° C （212° F）	熔点/凝固点	0° C （32° F）
分解温度	数据缺乏	pH 值	8 至 8.3 （固体和其他液体试剂）
比重/相对密度	数据缺乏	水溶解度	数据缺乏
粘度	数据缺乏	易爆性质	数据缺乏
氧化性性质：	数据缺乏		
挥发性			
蒸气压力	数据缺乏	蒸气密度	数据缺乏
蒸发速率	数据缺乏		
易燃性			
闪点	数据缺乏	爆炸上限	数据缺乏
爆炸下限	数据缺乏	自燃点	数据缺乏
易燃性（固体、气体）	数据缺乏		
环境方面			
辛醇/水分配系数	数据缺乏		

9.2 其他信息

未注明额外的物理和化学参数。

第 10 章：稳定性和反应性

10.1 反应性

在正常使用条件下，未知有危险反应。

10.2 化学稳定性
稳定

10.3 危险反应的可能性
不会发生危险的聚合反应。

10.4 应避免的情况
热、水分（影响产品质量）

10.5 不相容的材料
酸、氧化剂。

10.6 危险的分解产物
碳氧化物、钾氧化物。

第 11 章：毒物学信息

11.1 有关毒物学效应的信息

组成成分		
氯化铵（20% 至 30%）	12125-02-9	**急性毒性:**摄入/口服-大鼠 LD50 • 1650 mg/kg **刺激:** 眼-兔 • 100 mg • 严重刺激
碳酸钾（1% 至 5%）	584-08-7	**急性毒性:**摄入/口服-大鼠 LD50 • 1870 mg/kg **多剂量毒性:** 吸入-大鼠 TCLo • 43 mg/m³ 17 周；*心脏*：**心电图改变不是上述的诊断依据**；*肾、输尿管和膀胱*：**尿液成分的其他改变**；*营养和总代谢：化学成分或温度改变*: K；**诱变剂:**非程序 DNA 合成 • 摄入/经口-大鼠 • 504 g/kg 4 周-连续

GHS 危险种类	危险类别
急性毒性	EU/CLP•缺乏数据 UN GHS 3•急性毒性 - 经口 5 - ATEmix（经口） = 4795 mg/kg OSHA HCS 2012•缺乏数据
皮肤腐蚀/刺激	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
严重眼损伤/刺激	EU/CLP•眼刺激 2 UN GHS 3•眼刺激 2 OSHA HCS 2012•眼刺激 2
皮肤过敏	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
呼吸过敏	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
吸入危险	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据

GHS 危险种类	危险类别
致癌性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
生殖细胞致突变性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
针对生殖的毒性	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-SE	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据
STOT-RE	EU/CLP•缺乏数据 UN GHS 3•缺乏数据 OSHA HCS 2012•缺乏数据

潜在健康影响

吸入
急性（立即） 无可用数据
慢性（缓发） 无可用数据
皮肤
急性（立即） 无可用数据
慢性（缓发） 无可用数据
眼睛
急性（立即） 造成严重的眼刺激。
慢性（缓发） 无可用数据
摄入
急性（立即） 如果吞入可能是有害的。
慢性（缓发） 无可用数据

略语表
LD = 致死剂量
TC = 毒性浓度

第 12 章：生态学信息

12.1 毒性

	CAS	
Xpert Urine Specimen Collection Kit（Xpert 尿液样本采集工具包）、Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）	NDA	**水生毒性-鱼：** 4 天 LC50 *大西洋银汉鱼* 0.14 mg/L 注释：氯化铵 (12125-02-9) 30 天 NOEC *斑点叉尾鮰* 0.006 mg/L 注释：氯化铵 (12125-02-9) **水生毒性-水生贝壳类：** 2 天 EC50 *介形类* 0.075-0.126 mg/L 注释：氯化铵 (12125-02-9) 21 天 NOEC *水蚤* 0.05 mg/L 注释：氯化铵 (12125-02-9) **水生毒性 - 藻类等水生植物：** 3 天 EC50 *海王星项链（Neptune’s Necklace）藻* 0.04-0.1 mg/L 注释：氯化铵 (12125-02-9)

对水生生物有毒。对水生生物有毒，具有长期持续效应。

12.2 持久性和降解性
材料数据缺失。

12.3 生物累积的潜力
材料数据缺失。

12.4 土壤中的移动性
材料数据缺失。

12.5 PBT 及 vPvB 评估的结果
尚未进行 PBT 和 vPvB 评估。

12.6 其他不良效应
未发现研究成果。

第 13 章：处置注意事项

13.1 废物处理方法
产品废物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。
包装废弃物 与地方，区域，国家和/或国际法规的规定处理的内容和/或容器。

13.2 其他信息
生物样本，包括废盒子，应以能够传播感染源对待。咨询您所在机构的环保废物处理人员有关妥善处置用过盒子和未用过试剂的信息。本材料可能会表现出联邦环保署（EPA）资源保护与回收法（RCRA）危险废料的特征，要求采用特定的处置规定。请查阅国家和当地法规，因为它们可能不同于联邦的处置法规。美国以外的机构应查阅其本国的危险废料处置规定。

第 14 章：运输信息

	14.1 UN 编号	14.2 UN 正式运输名称	14.3 运输危险分类	14.4 包装组	14.5 环境危害
DOT	不适用	未管制	不适用	不适用	NDA
TDG	UN3082	对环境有害物质，液体，未另列明（氯化铵）	9	III	NDA
IMO/IMDG	UN3082	对环境有害物质，液体，未另列明（氯化铵）	9	III	NDA
IATA/ICAO	UN3082	对环境有害物质，液体，未另列明（氯化铵）	9	III	NDA

14.6 用户特殊防护措施
未列明。

14.7 根据 MARPOL 73/78 的附件 II 以及 IBC 规范规定的散装运输
缺乏数据。

安全数据表

生效日期：2020 年 2 月
更换日期：2016 年 7 月

Xpert Urine Specimen Collection Kit（Xpert 尿液样本采集工具包）
Xpert CT/NG Urine Specimen Collection Kit（Xpert CT/NG 尿液样本采集工具包）

第 15 章：法规信息

15.1 针对特定物质或混合物的安全、卫生和环境条例/法规

SARA 危险性分类 急性

名录						
成分	**CAS**	**加拿大 DSL**	**加拿大 NDSL**	**欧盟 EINECS**	**欧盟 ELNICS**	**TSAC**
氯化铵	12125-02-9	是	否	是	否	是
碳酸钾	584-08-7	是	否	是	否	是

加拿大

劳动

加拿大 - 加拿大工作场所危险物质信息系统 (WHMIS) - 物质分类

•碳酸钾	584-08-7	D2B, E
•氯化铵	12125-02-9	D2B

加拿大 - 加拿大工作场所危险物质信息系统 (WHMIS) - 组分披露列表

•碳酸钾	584-08-7	1%
•氯化铵	12125-02-9	1%

环境

加拿大 - 环境保护法 (CEPA) - 优先重点物质列表

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

United States

劳动

美国 - 职业安全与健康管理局 (OSHA) - 制程安全管理 - 高度危险化学品

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 职业安全与健康管理局 (OSHA) - 专门监管化学品

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

环境

美国 - CAA（清洁空气法）- 1990 年危险空气污染物

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 危险物质及其可报告数量

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	5000 lb 最终可报告数量；2270 kg 最终可报告数量

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 放射性核素及其可报告数量

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质 EPCRA RQ

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 302 节极端危险物质 TPQ

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - 排放报告

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 赔偿及责任法案 (CERCLA)/超级投资修正与重新授权法 (SARA) - 第 313 节 - PBT 化学品列表

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 加利福尼亚

环境

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 致癌物清单

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 发育毒性

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 最大容许剂量水平 (MADL)

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 无显著风险级别 (NSRL)

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 女性

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

美国 - 加利福尼亚州 - 第 65 号提案 (Proposition 65) - 生殖毒性 - 男性

•碳酸钾	584-08-7	未列出
•氯化铵	12125-02-9	未列出

15.2 化学安全评估

未进行化学安全评估。

第 16 章：其他信息

相关语词（代码及全文）

H302 - 如果吞入是有害的

免责声明/责任声明

以上信息基于对于我们的可用数据，而且相信是正确的。由于对信息的应用可能会在超出我们控制的条件下和以我们所不熟悉的条件进行，因此我们对其使用的任何结果概不承担任何责任，而且收到此信息的所有人士均务必自行确定其特定应用条件下的效能、性能、防护和处置方法。未就信息所涵盖的材料、其准确性、因使用材料而获得的结果或与使用材料相关的危害作出任何明示或暗示的表示、担保或保证（包括对特定目的下适用性或适销性的担保）。操作或使用本材料应小心谨慎。以上信息以诚信提供，而且相信是准确的。截至签发日期，我们提供有关可预见材料操作的所有信息。然而，一旦发生与本品相关的恶性事故，本安全数据表却不是，而且也不旨在是向接受过适当训练人员咨询的替代。请提供免责声明。

略语表

NDA = 无可用数据

安全データシート
発効日: 2020 年 2 月
優先日付: 2016 年 7 月

Xpert Urine Specimen Collection Kit
Xpert CT/NG Urine Specimen Collection Kit

セクション 1:物質・混合物、および企業・事業の識別

1.1 製品識別子

製品名 Xpert Urine Specimen Collection Kit、Xpert CT/NG Urine Specimen Collection Kit
製品コード CT/NGURINE-50; URINE/A-50

1.2 物質や混合物の特定された関連用途、および推奨されない用途

特定された関連用途 研究用

1.3 安全データを提供した供給業者の詳細

製造業者 Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US:techsupport@cepheid.com
電話(一般) 1 (888) 838-3222 -米国オプション 2
電話(一般) 1 (408) 541-4191 -米国外

供給業者 Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
EU:support@cepheideurope.com
電話(一般) +33 563 825 319

1.4 緊急電話番号

製造業者 + 1 (800) 535-5053 - INFOTRAC - 24 時間緊急電話
製造業者 + 1 (352) 323-3500-米国外

セクション 2:危険性識別

EU/EEC

準拠: 指令(EC)1272/2008 (CLP)/REACH 1907/2006 [453/2010 による改訂]

2.1 物質や混合物の分類

CLP 次の SDS は研究所で使用されるため、最終製品でのみ使用されます。液体物質を含み、その一部は凍結乾燥粉末およびカートリッジやナルゲンボトルに含まれた試薬である場合があります。すべての試薬は、透明で無色の液体です。一部の物質の情報の開示の免除は、CLP 項目 1(5)(d) および 29 CFR 1910.1200(g)(2)(i)(C)(1)と(2)に従っています。
眼刺激 2 - H319

2.2 ラベル要素

CLP

警告

危険有害性情報 H319 – 目に重度の刺激を引き起こす。

予防情報

予防 P264 – 取り扱いの後、十分に洗う。
P280 – 防護手袋／防護服／防護めがね／保護面を着用する。

応答 P305+P351+P338 – 目に入った場合: 数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
P337+P313 – 目への刺激が続く場合: 医師の助言／手当てを受ける。

2.3 その他危険性

CLP 規定(EC) No. 1272/2008 (CLP) に準じて、本剤は危険物とみなされます。

UN GHS 改訂第 3 版

準拠:UN 化学品の分類および表示に関する世界調和システム(GHS)
改訂第 3 版

2.1 物質や混合物の分類

UN GHS

急性毒性 経口 5
眼刺激 2
水性環境有害性 急性毒性 1
水性環境有害性 慢性毒性 1

2.2 ラベル要素

UN GHS

警告

危険有害性情報
飲み込むと有害。
目に重度の刺激を引き起こす。
水生生物に対してきわめて有害。
水生生物に対してきわめて有毒で、影響が長期に及ぶ。

予防情報

予防
取り扱いの後、十分に洗う。
環境への放出を避ける。
防護手袋／防護服／防護めがね／保護面を着用する。

応答 目に入った場合: 数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目の刺激が続く場合:医師の助言／手当てを受ける。
気分が悪い場合、毒物センターあるいは医師に連絡する。
流出物を集める。

保管・処分 地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

2.3 その他危険性

UN GHS 危険化学品分類表示の世界調和システム(GHS)では、本製品は危険な物質と考慮されています。

米国(US)

準拠: OSHA 29 CFR 1910.1200 HCS

2.1 物質や混合物の分類

OSHA HCS 2012 眼刺激 2

2.2 ラベル要素

OSHA HCS 2012

警告

危険有害性情報 目に重度の刺激を引き起こす。

予防情報

予防 取り扱いの後、十分に洗う。
防護手袋／防護服／防護めがね／保護面を着用する。

応答 目に入った場合: 数分間水で慎重にすすぐ。安全にはずせる場合は、コンタクトレンズをはずす。その後、すすぎを続ける。
目の刺激が続く場合:医師の助言／手当てを受ける。

2.3 その他危険性

OSHA HCS 2012 米国規定(29 CFR 1910.1200 - 危険有害性周知基準)に基づき、本製品は危険物とみなされます。

カナダ

準拠: WHMIS

2.1 物質や混合物の分類

WHMIS その他の毒性効果 - D2B

2.2 ラベル要素

WHMIS

その他の毒性効果 – D2B

2.3 その他危険性

WHMIS

カナダでは、上述の製品は作業場にある危険物に関する情報システム (WHMIS)に基づき危険物とみなされています。

2.4 その他情報

その他のすべての試薬、ビーズ、その他の成分は、混合物の 1%未満であるか、または米国ハザード通信規制(29 CFR 1910.1200)、物質または混合物の分類と表示に関する EU 指令、または物質または混合物の分類と表示に関する世界調和システムで有害とみなされていない。

セクション 3: 成分の組成・情報

3.1 物質

本剤は、材料区分を満たしません。

3.2 混合物

合成物					
化学名	**識別子**	**%**	**LD50/LC50**	**規定/指針に基づく分類**	**コメント**
塩化アンモニウム	**CAS:** 12125-02-9 **EC 番号:** 235-186-4 **EU 索引:** 017-014-00-8	20%～30%	摂取/経口-ラット LD50・1650 mg/kg	**EU CLP:** 添付書類 VI、表 3.1:急性毒性 4 *, H302; 眼の刺激 2、H319 **UN GHS Rev. 3:** 急性毒性 4(経口)、目のかゆみ 2、水生急性毒性 1、水生慢性毒性 1 **OSHA HCS 2012:** 急性毒性 4(経口)、目のかゆみ 2	NDA
炭酸カリウム	**CAS:** 584-08-7 **EC 番号:** 209-529-3	1%～5%	摂取/経口-ラット LD50・1870 mg/kg	**EU CLP:** 急性毒性 4, H302 **UN GHS 改訂第 3 版** 急性毒性 4(経口)、目のかゆみ 2B **OSHA HCS 2012:** 急性毒性 4(経口)、目のかゆみ 2B	NDA

H-statement の全文については、第 16 節を参照してください。

セクション 4: 応急処置手段

4.1 応急措置手段

吸引

物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。被災者を新鮮な空気がある場所に移す。呼吸困難の場合は酸素を供給する。被災者が物質を吸引した場合、口移し式人工呼吸を行ってはならない; 一方向バルブの付いたポケットマスクや、その他の適切な呼吸医療装置を使って人工呼吸を行う。被災者が呼吸していない場合は、人工呼吸を施す。

皮膚	物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。軽度の皮膚との接触では、影響を受けていない皮膚に物質を広げないようにする。物質と接触した場合は、最低 20 分間、直ちに流水で皮膚を洗浄する。汚染した衣類を取り除いて隔離する。
目	物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。物質と接触した場合は、最低 20 分間、直ちに流水で目を洗浄する。目の刺激が続く場合：医師の助言／手当てを受ける。
摂取	物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されません。飲み込んだ場合は、水で口をゆすいでください（意識がある場合）。嘔吐を誘発しないでください。被災者が物質を摂取した場合は口移し式人工呼吸を行ってはならない。摂取した場合は直ちに医師の手当てを受ける。

4.2 もっとも重要な症状と影響、急性および遅発性

第十一項 毒性に関する情報を参照してください。

4.3 直ちに医学的配慮と特別治療を必要とする兆候

医師へのメモ	治療はすべて、患者の苦痛の兆候および症状に基づき行われる必要があります。本製品以外の物質に著しくさらされた可能性について考慮する必要があります。

セクション 5：消化手段

5.1 消火剤

適切な消火剤	大規模火災：乾燥した化学品、二酸化炭素、耐アルコール泡消火剤、散水 小規模火災：乾燥した化学品、二酸化炭素、散水
不適切な消火剤	データなし

5.2 物質や混合物から発生する特別な危険

異常な火災と爆発の危険	炭素酸化物、窒素酸化物の有毒な蒸気を放出することがあります。
有害な燃焼生物	データなし

5.3 消防士への助言

建物火災用消防用服が火災状況で提供する保護は限定されている; 流出した状況では物質に直接接触する可能性があるため、効果がない。
製造業者が推奨する化学品防護服を着用する。熱に対する保護は、ある程度、またはまったく提供されない。
陽圧自給式呼吸器（SCBA）を着用する。
小規模火災：危険を冒さずにできる場合は、火災区域から容器を移動させる動かす。

セクション 6：漏出時の措置

6.1 人体に対する注意事項、保護具、および緊急時措置

人体に対する注意事項	カートリッジが破損した場合、これらの人体に対する予防措置が適用されます。適切な保護服を着用する。漏出した物質を通って歩かない。適切な保護服を着用せずに破損した容器または漏出した物質に触れてはならない。閉じ込められた場所を換気する。
応急措置	物質が通常の状況でかつ推奨通りに使用される場合、救急措置が必要であることは予測されない。

6.2 影響に対する注意事項

水路、下水道、地下室、囲まれた区域に流入するのを防ぐ。

6.3 閉じ込めと清掃の手段と物質

閉じ込め・清掃の手段 少量の流出の場合は、手袋を着用し、ペーパータオルで流出を吸収してください。流出した物質を排水溝に廃棄しないでください。

6.4 他のセクションへの言及

第八項 爆発管理/安全保護、および第十三項 廃棄時の注意事項を参照してください。

セクション 7: 取り扱いと保管

7.1 安全な取り扱いについての注意

取り扱い 特別な取扱いは必要ありません。カートリッジが破損した場合、漏出した試薬に触れないようにしてください。皮膚に付着したり、目に入らないようにしてください。

7.2 安全な保管の条件、不適合性を含む

保管 製品ラベルに従って保管してください。容器/パッケージをしっかりと密閉し、涼しく、風通しの良い場所に保管してください。互換性をもたない物質から離す。

7.3 具体的な最終用途

セクション 1.2 関連する使用方法に関する情報を参照してください。

セクション 8: 暴露管理・個人保護

8.1 管理パラメータ

曝露限度／ガイドライン			
	結果	ACGIH	NIOSH
塩化アンモニウム (12125-02-9)	STEL	20 mg/m3 STEL（蒸気）	20 mg/m3 STEL（蒸気）
	TWAs	10 mg/m3 TWA（蒸気）	10 mg/m3 TWA（蒸気）

8.2 曝露管理

工学的手段・管理 十分な通気を確保してください。通規率は状況に応じて適切に調整してください。該当する場合は、包囲装置、局所排気装置、またはその他のエンジニアリングコントロール装置を使って、空気中の粉塵レベルが推奨暴露限界を超えないようにしてください。暴露レベルが確定されていない場合は、許容範囲の粉塵量を維持してください。

個人用保護具

呼吸器官 OSHA 呼吸器規制に関しては、29 CFR 1910.134 または 欧州標準 EN 149 をご覧ください。暴露基準を超える場合、あるいは症状が発症した場合は、NIOSH/MSHA または 欧州標準 EN 149 保護マスクをご使用ください。

目・顔面 化学物飛散防止ゴーグルを着用してください。

皮膚・人体	研究所での服装として、手袋とラボコートを最低限着用し、皮膚接触を最小化してください。
環境暴露管理	現場管理および廃棄物の取り扱いは十分注意して行ってください。

略語について

ACGIH = 米国産業衛生専門家会議
NIOSH = 独立行政法人労働安全衛生総合研究所
OSHA = 労働安全衛生局
STEL = 短時間暴露限度とは、15 分間をベースとして暴露限度です。
TWA = 時間加重平均値は、8 時間/1 日、40 時間/1 週間の暴露に基づいた数値です。

セクション 9：物理的および化学的特性

9.1 物理的および化学的特性

材料の説明			
物理的形状	液体	外観/記述	試薬は、主に水溶液で緩衝された、透明、無色、無臭の液体である。
色	透明	臭気	無臭
臭気限界	データ不足		
一般的性質			
沸騰点	100° C（212° F）	融解点・凝固点	0° C（32° F）
分解温度	データ不足	pH	8 ～8.3 （固体およびそのほかの液体試薬）
比重・相対密度	データ不足	水溶性	データ不足
粘性	データ不足	爆発特性	データ不足
酸化特性：	データ不足		
揮発度			
蒸気圧	データ不足	蒸気密度	データ不足
蒸発速度	データ不足		
可燃性			
引火点	データ不足	UEL	データ不足
LEL	データ不足	自己発火	データ不足
可燃性（固体、ガス）	データ不足		
環境曝露管理			
オクタノール・水分配係数	データ不足		

9.2 その他情報

その他に物理的および化学的パラメータの記載はありません。

セクション 10：安定性と反応性

10.1 反応性

通常の使用において、危険反応は報告されていません。

10.2 化学安定性

安定

10.3 有害反応の可能性

危険物のポリメリゼーションは発生しません。

10.4 回避すべき条件

熱、湿気（製品品質に影響を与えます）

10.5 不適合物質

酸、酸化試薬

10.6 有害分解性生物

炭素酸化物、カリウム酸化物。

セクション 11: 毒性情報

11.1 毒性効果

成分		
塩化アンモニウム(20%～30%)	12125-02-9	**急性毒性**: 摂取/経口-ラット LD50・1650 mg/kg **刺激**: 眼-ウサギ・100 mg・重度の刺激、
炭酸カリウム(1%～5%)	584-08-7	**急性毒性**: 摂取/経口-ラット LD50・1870 mg/kg **複数用量毒性**: 吸入-ラット TCLo・43 mg/m³ 17 週; *心臓*: **EKG 変化は上記の診断ではない**; *腎臓、尿管、および膀胱*: **尿成分で他の変化**; *化学または温度で栄養および総代謝の変化*: **K**; **変異原**: 不定期 DNA 合成・摂取/経口-ラット・504 g/kg 4 週-継続的

GHS 特性	分類
急性毒性	EU/CLP-データ不足 UN GHS 3-急性毒性 - 経口 5 - ATEmix（経口）= 4795 mg/kg OSHA HCS 2012-データ不足
皮膚の腐食・炎症	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
重度の目の損傷・炎症	EU/CLP-目の炎症 2 UN GHS 3-目の炎症 2 OSHA HCS 2012-目の炎症 2
皮膚感作性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
呼吸器感作性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
吸引有害性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
発癌性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足

GHS 特性	分類
生殖細胞変異原性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
生殖毒性	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
STOT-SE	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足
STOT-RE	EU/CLP-データ不足 UN GHS 3-データ不足 OSHA HCS 2012-データ不足

考えられる健康への影響

吸引
急性(即座) データなし
慢性(遅発性) データなし
皮膚
急性(即座) データなし
慢性(遅発性) データなし
目
急性(即座) 目に重度の炎症を起こす。
慢性(遅発性) データなし
摂取
急性(即座) 飲み込んだ場合、健康に支障を生じる可能性があります。
慢性(遅発性) データなし

略語について
LD = 致死量
TC = 毒性濃度

セクション 12: 生態学的情報

12.1 毒性

	CAS	
Xpert Urine Specimen Collection Kit、Xpert CT/NG Urine Specimen Collection Kit	NDA	**水生生物毒性-魚類:** 4 日 LC50 *大西洋トウゴロイワシ* 0.14 mg/L コメント: 塩化アンモニウム (12125-02-9) 30 日 NOEC *アメリカナマズ* 0.006 mg/L コメント: 塩化アンモニウム (12125-02-9) **水生生物毒性-甲殻類:** 2 日 EC50 *貝虫類* 0.075-0.126 mg/L コメント: 塩化アンモニウム (12125-02-9) 21 日 NOEC *ミジンコ* 0.05 mg/L コメント: 塩化アンモニウム (12125-02-9) **水生生物毒性-藻類およびその他の水生植物:** 3 日 EC50 *藻類 Neptune's Necklace* 0.04-0.1 mg/L コメント: 塩化アンモニウム (12125-02-9)

水中生物に毒性を発します。水生生物に対して有毒で、影響が長期に及ぶ。

12.2 持続性と分解性
実態データが不足しています

12.3 生体内蓄積能
実態データが不足しています

12.4 土壌中移動性
実態データが不足しています

12.5 PBT と vPvB 評価の結果
PBT および vPvB アセスメントは行われていません。

12.6 その他有害影響
そのような研究結果はありません。

セクション 13：廃棄上の注意

13.1 廃棄物処理手段

製品廃棄物	地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。
包装廃棄物	地方、地域、国、および/または国際的な規則に従ってコンテンツ及び/または容器に廃棄してください。

13.2 その他情報
使用済みカートリッジなどの生物試料は、感染物質を伝染する能力があるものとして取り扱われる必要があります。使用済みカートリッジと未使用の試薬の適切な廃棄方法については、機関の環境廃棄物担当員に相談してください。この資料は、特別な廃棄要件をもつ連邦 EPA 資源保全再生法（RCRA）の危険廃棄物の特性を示している場合があります。州と地方の規則については、連邦の廃棄方法の規則と異なる場合があるので、ご確認ください。米国外の機関では、その国の危険廃棄物処理方法の要件をご確認ください。

セクション 14：輸送情報

	14.1 UN 番号	14.2 UN 正式輸送品目名	14.3 輸送有害性等級	14.4 包装等級	14.5 環境有害性
DOT	該当なし	規制なし	該当なし	該当なし	NDA
TDG	UN3082	環境有害物質、液体、N.O.S.（塩化アンモニウム）	9	III	NDA
IMO/IMDG	UN3082	環境有害物質、液体、N.O.S.（塩化アンモニウム）	9	III	NDA
IATA/ICAO	UN3082	環境有害物質、液体、N.O.S.（塩化アンモニウム）	9	III	NDA

14.6 ユーザーに対する特別予防装置
指定なし。

14.7 MARPOL 73/78 附属書 II と IBC コードに則ったバルク輸送
データ不足。

安全データシート

発効日: 2020 年 2 月
優先日付: 2016 年 7 月

Xpert Urine Specimen Collection Kit
Xpert CT/NG Urine Specimen Collection Kit

セクション 15:規制情報

15.1 物質や混合物についての具体的な安全、健康、環境規制・法律

SARA 危険分類 急性

			在庫			
成分	**CAS**	**カナダ DSL**	**カナダ NDSL**	**EU EINECS**	**EU ELNICS**	**TSCA**
塩化アンモニウム	12125-02-9	あり	なし	あり	なし	あり
炭酸カリウム	584-08-7	あり	なし	あり	なし	あり

カナダ

作業

カナダ - WHMIS - 物質の分類

·炭酸カリウム	584-08-7	D2B、E
·塩化アンモニウム	12125-02-9	D2B

カナダ - WHMIS -成分開示リスト

·炭酸カリウム	584-08-7	1%
·塩化アンモニウム	12125-02-9	1%

環境

カナダ - CEPA- 優先物質リスト

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

United States

作業

米国 OSHA - プロセス安全管理 - 非常に危険有害な化学品

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国 OSHA - 特異制御化学物質

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

環境

米国- CAA (大気汚染防止法) - 1990 有害大気汚染物質

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国- CERCLA/SARA - 有害危険物質および報告義務量

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	最終 5000 ポンド RQ; 最終 2270 kg RQ

米国- CERCLA/SARA - 放射性核種および報告義務量

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国- CERCLA/SARA 第 302 項 極めて有害な物質 EPCRA の報告義務量

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国- CERCLA/SARA 第 302 項 極めて有害な物質 TPQ

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国- CERCLA/SARA 第 313 項 排気量レポート

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国- CERCLA/SARA 第 313 項 排出報告

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国 - カリフォルニア

環境

米国カリフォルニア州住民投票事項 65-発がん性物質リスト

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国カリフォルニア州住民投票事項 65-発達毒性

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国カリフォルニア州住民投票事項 65-最大許容レベル(MADL)

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国カリフォルニア州住民投票事項 65-無リスク(安全)摂取量(NSRL)

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国カリフォルニア州住民投票事項 65-生殖毒性-女性

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

米国カリフォルニア州住民投票事項 65-生殖毒性-男性

·炭酸カリウム	584-08-7	掲載外
·塩化アンモニウム	12125-02-9	掲載外

15.2 化学物質安全評価

化学的安全評価は実施されていません。

セクション 16:その他情報

関連表現(コードと全文)

H302 – 飲み込むと有害。

免責条項/責任声明

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略語について
NDA = 該当データなし。