

Rheumatology

5/23/2021

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Safety Data Sheet

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

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

1.1. Product identifier

Product name ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

Product code SAP-10130495

Synonyms

- Actemra 20 mg/ml concentrate for solution for infusion
- ACTEMRA(R) Vials (80 mg)

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

Use

- pharmaceutical active substance (antirheumatic) *1
- for intravenous infusion after dilution

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	Local representation:

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

*1 referring to: Tocilizumab

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification no classification and labelling according to GHS

Other hazards

Note

- no information available

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

SECTION 3: Composition/information on ingredients

Characterization tocilizumab with other inactive ingredients
1 vial contains 80 mg tocilizumab

Ingredients	Concentration	GHS-Classification (pure ingredient)

Tocilizumab 375823-41-9	2 %	

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note	- no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	- no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - rinse with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- do not freeze
- protected from light

Validity - see "best use before" date stated on the label, after opening the content should be used within a short period

Packaging materials - vials
- keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.4 mg/m³ *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary during normal operations

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

Eye protection - safety glasses

*1 referring to: Tocilizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color colorless to slightly yellow
clear to opalescent

Form clear solution
sterile liquid

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability

- does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution
- as for all other proteins, monoclonal antibodies are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid

- warming
- light
- heavy mechanical loads (shock, impact)

10.5. Incompatible materials

Note - no information available

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- NOEL ≥ 150 mg/kg (i.v., rat)	*1
	- not bioavailable by oral administration	*1
Subacute toxicity	- NOAEL 10 mg/kg/d (i.v., rat, 28 d)	*1
Sensitization	- anaphylactic reactions may occur following the intravenous application of proteins; after inhalative exposure no cases of hypersensitivity have been described	
Chronic toxicity	- NOAEL > 100 mg/kg/w (i.v., monkey; 6 months)	*1
Mutagenicity	- not mutagenic (various in vitro test systems)	*1
Note	- immunosuppressive agent	*1
	- therapeutic dose: 4 to 8 mg/kg/month	*1
	- elimination half-life: 6 to 9 d	*1
	- side effect(s) during therapy: liver damages, infectious episodes	*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: formulation not listed by NTP, IARC or OSHA	
Additional Health Information	- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class.	
*1 referring to:	Tocilizumab	

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l) (<i>Daphnia magna</i>) EC ₅₀ (48 h) > 100 mg active substance/l NOEC (48 h) 100 mg active substance/l (OECD No. 202)	*2
	- barely toxic for fish (nominal concentration = 100 mg/l) (zebrafish) LC ₅₀ (96 h) > 100 mg active substance/l NOEC (96 h) 100 mg active substance/l (OECD No. 203)	*2
	- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg active substance/l (Manometric Respirometry Test, OECD No. 301 F)	*2

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

- barely toxic for algae (nominal concentration = 100 mg/l)
(Scenedesmus (=Desmodesmus) subspicatus)
EC₅₀ (72 h) > 100 mg active substance/l
NOEC (72 h) 100 mg active substance/l
(OECD No. 201) *2

12.2. Persistence and degradability

- Ready biodegradability
- readily biodegradable
89 % BOD/ThOD, 28 d
≥ 76 % active substance, 28 d
(Manometric Respirometry Test, OECD No. 301 F) *2

12.3. Bioaccumulative potential

- Note
- no information available

12.4. Mobility in soil

- Note
- no information available

12.5. Results of PBT and vPvB assessment

- Note
- no information available

12.6. Other adverse effects

- Note
- no information available

*2 referring to: ACTEMRA™ Sterile Concentrate for Injection (80, 200 & 400 mg)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste from residues
- observe local/national regulations regarding waste disposal
 - drain very small quantities into wastewater treatment plant

SECTION 14: Transport information

- Note
- not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

- TSCA Status
- FDA Exemption - not on inventory

ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

Reporting Requirements

- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note

- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation

- changes from previous version in sections 2, 3, 16

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.



Safety Data Sheet

ANTISEPTIC TOWELETTES

Section 1. Identification

Product Identifier	ANTISEPTIC TOWELETTES		
Synonyms	MDS094184; MDS094185		
Manufacturer Stock Numbers	MDS094184; MDS094185		
Recommended use	Cleanse intended area		
Uses advised against	N/A		
Manufacturer Contact Address	Medline Industries, Inc. One Medline Place Mundelein, IL, 60060 USA		
	Phone (800) 633-5463	Emergency Phone (800) 424-9300 CHEMTREC CHEMTREC	Fax (847) 643-4436
	Website www.Medline.com		

Section 2. Hazards Identification

Classification	ACUTE TOXICITY - DERMAL - Category 5 ACUTE TOXICITY - ORAL - Category 5 EYE DAMAGE/IRRITATION - Category 2B No OSHA Hazard Classifications Applicabl - Category N/A SENSITIZATION - SKIN - Category 1B
Signal Word	Warning
Pictogram	

Hazard Statements	Causes eye irritation May be harmful if swallowed May be harmful in contact with skin May cause an allergic skin reaction
Precautionary Statements	
Response	Call a poison center/doctor/ ... /if you feel unwell. If eye irritation persists: 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 on skin: Wash with plenty of water/ ... If skin irritation or rash occurs: Get medical advice/attention. Specific treatment (see ... on this label) Wash contaminated clothing before reuse.
Prevention	Avoid breathing dust/fume/gas/mist/ vapors/spray. Contaminated work clothing must not be allowed out of the workplace. Wash ...thoroughly after handling. Wear protective gloves.
Storage	N/A
Disposal	Dispose of contents/container to ...
Ingredients of unknown toxicity	0%
Hazards not Otherwise Classified	No Data Available

Section 3. Ingredients

CAS	Ingredient Name	Weight %
8001-54-5	Benzalkonium Chloride	0.13 %
67-63-0	Isopropyl alcohol	5 %

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-Aid Measures

General Advice:	Take proper precautions to ensure your own health and safety before attempting rescue and providing first aid. Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
Eye Contact:	Flush eyes with large amounts of water for at least 15 minutes. Remove contact lenses, if worn. If irritation persists, seek medical attention.
Skin Contact:	Wash with soap and water; if irritation persists, seek medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get immediate medical attention.
Ingestion:	If swallowed, call a physician immediately. Rinse mouth and throat thoroughly with water. Do not induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. If vomiting occurs spontaneously, keep head below hips to prevent aspiration of liquid into lungs. If patient is conscious and alert, give large amounts of water. Get medical attention.

Section 5. Fire Fighting Measures

Suitable Extinguishing Media	In case of fire, use Carbon Dioxide (CO2) or Dry Chemical
Unsuitable Extinguishing Media	None known
Special Fire Fighting Procedures:	Self contained breathing apparatus and full protective clothing recommended.
Unusual Fire and Explosive Hazards:	None known

Section 6. Accidental Release Measures

Non-hazardous Small Spill:	Should be cleaned up at the time of the spill. Take all necessary precautions and wear any personal protective equipment that is applicable. Dispose of per local and state regulations.
Non-hazardous Large Spill:	Should be cleaned up at the time of the spill. May require special treatment, equipment and/or emergency assistance. Dispose of per local and state regulations.

Section 7. Handling and Storage

Handling Non-hazardous:	This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions.
Storage Non-hazardous:	Store in original package. Discard unused portion. Do not reuse. No special storage conditions required.

Section 8. Exposure Controls/Personal Protection

Occupational Exposure Limits	Ingredient Name	ACGIH TLV	OSHA PEL	STEL
	Benzalkonium Chloride	N/A	N/A	N/A
	Isopropyl alcohol	TWA: 200 ppm STEL: 400 ppm	TWA: 400 ppm STEL: 500 ppm	N/A
Personal Protective Equipment	Respirator			
Engineering Controls:	Ventilation:			
Respiratory Protection:	Respiratory protection may be worn if ventilation does not eliminate symptoms or keeps levels below recommended exposure limits. If exposure limits are exceeded, wear: NIOSH-Approved organic respirator. NIOSH-Approved Supplied Air Respirator (SAR). NIOSH-Approved self-contained breathing apparatus. Do not exceed limits established by the respirator manufacturer. All respiratory protection programs must comply with OSHA 29 CFR 1910.134 and ANSI Z88.2 requirements and must be followed whenever workplace conditions require a respirator's use.			
Skin Protection:	Wear protective gloves			
Eye Protection:	Wear chemical safety goggles while handling this product. Do not wear contact lenses. Wear additional eye protection such as face shield when the possibility exists for eye contact with splashing or spraying liquid, or airborne material.			
Other protective equipment:				
Work/hygienic practices:	Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Safety shower and eye wash should be available close to work areas.			

Section 9. Physical and Chemical Properties

Physical State	Liquid
Color	Colourless transparent solution
Odor	Fragrance odour
Odor Threshold	N.D.
Solubility	Soluble
Partition coefficient Water/n-octanol	N.D.
VOC%	N/A
Viscosity	N.D.
Specific Gravity	0.98
Density lbs/Gal	0.9
Pounds per Cubic Foot	N/A
Flash Point	N.D.
FP Method	N.D.
Ph	6.99
Melting Point	N.D.
Boiling Point	180° F
Boiling Range	N.D.
LEL	N/A
UEL	N/A
Evaporation Rate	7
Flammability	N.D.
Decomposition Temperature	N.D.
Auto-ignition Temperature	N.D.
Vapor Pressure	N.D.
Vapor Density	> 2.0

Section 10. Stability and Reactivity

Stability:	Stable.
Reactivity:	Stable under normal conditions
Incompatibility (Materials to Avoid):	Strong oxidizing agents. Strong acids
Hazardous Decomposition or Byproducts:	Upon decomposition, this product may yield oxides of nitrogen and ammonia
Hazardous Polymerization	N.D.
Conditions to avoid:	Strong oxidizing agents. Strong acids

Section 11. Toxicological Information

Acute Toxicity: Eye Contact	Causes acute eye irritation/damage
Acute Toxicity: Skin Contact	May cause irritation and/or redness.
Acute Toxicity: Inhalation	N.D.
Acute Toxicity: Ingestion	May cause irritation to mouth, throat and upset the gastrointestinal tract
Chronic Toxicity:	Diethanolamine, Cocamide DEA, components of this product, have been designated by IARC as possibly carcinogenic to humans.
Carcinogenicity:	IARC listed: Cocamide DEA (CAS#68603-42-9) IARC 2B IARC listed: Diethanolamine (CAS 111-42-2) IARC 2B
OSHA STEL:	N.D.
ACGIH TLV:	N.D.

Section 12. Ecological Information

Toxicity:	N.D.
Persistence and degradability:	N.D.
Bioaccumulative potential:	N.D.
Mobility in soil:	N.D.
Other adverse effects:	N.D.

Section 13. Disposal

Waste Disposal:	Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14. Transport Information

UN Number	N/A
UN Proper Shipping Name	Not Regulated
DOT Classification	Not Regulated
Packing Group	Not Regulated
IMDG:	Not regulated
IATA:	N.D.

Section 15. Regulatory Information

US Federal Regulations: General Product Information	N.D.
US Federal Regulations: Clean Air Act	This product does not contain any HAPs
US Federal Regulations: Component Analysis	N.D.
US Federal Regulations: Food & Drug Administration	N.D.
State Regulations: General Product Information	N.D.
State Regulations: Component Analysis	N.D.
Other Regulations:	N.D.
Other Classifications:	N.D.
WHMIS (Canada):	N.D.
California Prop.65:	N.D.
CERCLA:	N.D.
SARA Title III Section 311/312 Hazard class:	Acute Health Hazard
SARA Title III Section 313 Chemicals:	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.

Section 16. Other Information

Revision Date	5/29/2015
Legend	N.A. - Not Applicable N.E. - Not Established N.D. - Not Determined
Additional Information	The information contained herein is furnished without warranty or legal responsibility of any kind. Employers should use this information only as a supplement to other information gathered by them and must make independent determination of suitability and completeness of information from all sources to assure proper use of these materials and the safety and health of employees
Additional Information	NFPA 1-0-0



LABORATORIES, INC.

SAFETY DATA SHEET

Product Name: AQUASONIC® 100 ULTRASOUND
TRANSMISSION GEL

US Department of Labor
Occupational
Safety and Health Administration

SECTION 1 — CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: AQUASONIC® 100 ULTRASOUND TRANSMISSION GEL
(As used on label and List)

Manufacturer's Name: PARKER LABORATORIES INC.
Address: 286 ELDRIDGE ROAD
(number, street, City, State, Zip code) FAIRFIELD, NJ 07004 USA
Emergency Telephone Number: (800)-631-8888
Telephone Number for Information: (973)-276-9500 (8:30am – 5:15pm ET)

SECTION 2 — HAZARDS IDENTIFICATION

Hazardous Components (Specific Chemical Identity; Common Name(s)): NONE

Classification of the Substance/Mixture: NOT CLASSIFIED

Signal Word: N/A

Hazard Statements: NO KNOWN SIGNIFICANT EFFECTS OR CRITICAL HAZARDS

Precautionary Statement: HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE PRACTICES

OSHA Hazards: NO OSHA HAZARDS

SECTION 3 — COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients (specific)	% Composition	CAS Number
N/A	N/A	N/A

SECTION 4 — FIRST AID MEASURES

Signs and Symptoms of Exposure: N/A

Medical Symptoms Generally Aggravated by Exposure: NONE KNOWN

Emergency and First Aid Procedures:

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

Skin contact: In the case of skin irritation or allergic reactions, wash with soap and plenty of water. See a physician.

Eye contact: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Ingestion: If accidentally swallowed obtain immediate medical attention. Clean mouth with water and drink afterwards plenty of water. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.



SAFETY DATA SHEET

Product Name: AQUASONIC® 100 ULTRASOUND
TRANSMISSION GEL

US Department of Labor
Occupational
Safety and Health Administration

SECTION 5 — FIRE FIGHTING MEASURES

Flash Point(Method Used): NON-FLAMABLE Flammable Limits: N/A LEL: N/A UEL: N/A

Extinguishing Media: USE EXTINGUISHING MEDIA APPROPRIATE FOR SURROUNDING FIRE

Special Fire Fighting Procedures: NONE

Unusual Fire and Explosion Hazards: NONE

Protective Equipment and Precautions for Firefighters: WEAR A SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE GEAR.

SECTION 6— ACCIDENTAL RELEASE MEASURES

Leak and Spill Procedures: SLIPPERY IF SPILLED ON FLOOR. MIX WITH SWEEPING COMPOUND. MOP AREA WITH WATER.

Personal Precautions: N/A

Environmental Precautions: N/A

SECTION 7— HANDLING AND STORAGE

Handling procedures and Equipment: N/A

Storage requirements: NO SPECIAL PRECAUTIONS REQUIRED.

SECTION 8— EXPOSURE CONTROL/PERSONAL PROTECTION

Exposure Limits: ☐ ACGIH TLV ☐ OSHA PEL ☐ Other(Specify)

Specific Engineering Controls (such as ventilation, enclosed process) ENSURE ADEQUATE VENTILATION

Personal Protective Equipment:

☐ Gloves ☐ Eye ☐ Clothing ☐ Footwear ☐ Respirator ☐ Other (specify)

If checked, please specify type:

SECTION 9— PHYSICAL AND CHEMICAL PROPERTIES

Physical State(Appearance): Viscous, Aqueous Gel

Color: Clear Blue

Odor: Slight Fragrance

Specific Gravity(H₂O=1): 1.02

pH: 6.50-6.95

Solubility in Water: Soluble in water

Boiling point: N/D

Melting Point: N/D

Flammability(solid, gas): N/D



SAFETY DATA SHEET

Product Name: AQUASONIC® 100 ULTRASOUND
TRANSMISSION GEL

US Department of Labor
Occupational
Safety and Health Administration

Vapor Pressure(mm Hg): N/D
Vapor Density(AIR=1): N/D
Viscosity: 130,000-185,000cps
Density: N/D
Evaporation Rate(Butyl
Acetate= 1): N/D

SECTION 10 — STABILITY AND REACTIVITY

Stability: Unstable ☐ Conditions to Avoid: NONE
Stable ☒

Hazardous Decomposition or Byproducts: NONE

Incompatibility (Materials to Avoid): NONE

Hazardous Polymerization: May Occur? ☐ Will Not Occur? ☒

Conditions to Avoid: NONE

Reactivity: NO SPECIFIC TEST DATA RELATED TO REACTIVITY AVAILABLE FOR THIS PRODUCT.

SECTION 11 — TOXICOLOGICAL INFORMATION

Health Hazards (Acute and Chronic): NONE KNOWN

Route(s) of Entry: ☐ Skin Contact ☐ Eye Contact ☐ Inhalation ☒ Ingestion

Carcinogenicity: NTP? NO IARC Monographs? NO OSHA Regulated: NO

Signs and Symptoms of Exposure: N/A

Medical Conditions Generally Aggravated by Exposure: NONE KNOWN

SECTION 12 — ECOLOGICAL INFORMATION

Ecotoxicity: N/A

Persistence and Degradability: THERE IS NO DATA AVAILABLE FOR THIS PRODUCT

Bioaccumulative Potential: THERE IS NO DATA AVAILABLE FOR THIS PRODUCT

Mobility in the Soil: THERE IS NO DATA AVAILABLE FOR THIS PRODUCT

Additional Ecological Information: THERE IS NO DATA AVAILABLE FOR THIS PRODUCT

SECTION 13 — DISPOSAL CONSIDERATIONS

Waste Disposal:

FOLLOW ALL FEDERAL, STATE AND LOCAL REGULATIONS FOR NON-HAZARDOUS WASTE DISPOSAL.



SAFETY DATA SHEET

Product Name: AQUASONIC® 100 ULTRASOUND
TRANSMISSION GEL

US Department of Labor
Occupational
Safety and Health Administration

SECTION 14 — TRANSPORT INFORMATION

DOT Classification: NOT REGULATED
IMDG Classification: NOT REGULATED
TDG Classification: NOT REGULATED
IATA Classification: NOT REGULATED
RID: NOT REGULATED

SECTION 15 — REGULATORY INFORMATION

OSHA Hazards: NO OSHA HAZARDS
SARA 311/312 Hazards: NO SARA HAZARDS

SECTION 16 — OTHER INFORMATION

Date of Issue: 5/27/2015
Prepared By: Quality Assurance
Version: 1

***Disclaimer:** 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. No warranty, guarantee or representation is made as to the correctness and sufficiency of the information. It's the user's responsibility to determine safe conditions for the use of this product and to assume liability for loss, injury, or expense resulting from the misuse of this product.*



SAFETY DATA SHEET

1. Identification

Product identifier BENLYSTA

Other means of identification

Synonyms

BELIMUMAB 120MG/VIAL AND 400MG/VIAL * BELIMUMAB, FORMULATED PRODUCT

Recommended use

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOG)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
SUCROSE	SUGAR * CANE SUGAR * BEET SUGAR * CONFECTIONER'S SUGAR * ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL * GRANULATED SUGAR * SUCRALOX	57-50-1	< 50
BELIMUMAB		Unassigned	< 49
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARBOX YLIC ACID, MONOHYDRATE * CITRIC ACID MONOHYDRATE	5949-29-1	< = 0.10
Other components below reportable levels			< 2

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation

Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	None known.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Assume that this product is capable of sustaining combustion.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. 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	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. 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	Avoid prolonged exposure. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Components	Type	Value
BELIMUMAB (CAS Unassigned)	OHC	2
HYDROUS CITRIC ACID (CAS 5949-29-1)	8 HR TWA	5000 mcg/m3
	OHC	1

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties**Appearance**

Physical state Solid.

Form Lyophilised powder.Vial.

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 available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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) Not available.

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	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

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	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

None known.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use.

Respiratory or skin sensitization

Respiratory sensitization	Not established.
Skin sensitization	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

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	None known.
Specific target organ toxicity - repeated exposure	None known.
Aspiration hazard	Not likely, due to the form of the product.
Chronic effects	None known.
Further information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity	Not expected to be harmful to aquatic organisms.
Persistence and degradability	No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SUCROSE 69 % BOD5

Bioaccumulative potential**Partition coefficient n-octanol / water (log Kow)**

SUCROSE

-3

Mobility in soil

No data available.

Mobility in general**Volatility****Henry's law**

SUCROSE

< 0 atm m³/mol Estimated**Other adverse effects**

Not available.

13. Disposal considerations**Disposal instructions**

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

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). Avoid discharge into water courses or onto the ground.

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 a dangerous good.

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

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information**US federal regulations****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 - Yes

Delayed Hazard - No

Fire Hazard - Yes

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

SUCROSE (CAS 57-50-1)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

SUCROSE (CAS 57-50-1)

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)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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	02-27-2015
Revision date	02-27-2015
Version #	04
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 1 Instability: 0
References	GSK Hazard Determination

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Exposure Controls / Personal Protection:
Physical & Chemical Properties:
Transport Information:
Regulatory Information: United States



CaviCide™
Date Prepared: 3/23/16

SAFETY DATA SHEET

Section 1. Product And Company Identification

Product Name: CaviCide™

Product Use: Hard surface cleaner and disinfectant

Manufacturer: METREX™ RESEARCH
28210 Wick Rd
Romulus, MI 48174
U.S.A.

Information Phone Number: 1-800-841-1428 (Customer Service)

Chemical Emergency Phone Number (Chemical Spills, Leaks, Fire, Exposure or Accident only):
CHEMTREC 1-800-424-9300 (in the US) 1-703-527-3887 (Outside the US)

SDS Date Of Preparation/Revision: 3/23/16

Section 2. Hazards Identification

GHS / HAZCOM 2012 Classification:

Flammable Liquid Category 3

Eye Irritation Category 2A

Specific Target Organ Toxicity Single Exposure Category 3 (Narcotic effects)

Warning!



Hazard Phrases

Flammable liquid and vapor.

Causes serious eye irritation.

May cause drowsiness or dizziness.

Prevention:

Keep away from heat, sparks, open flames, hot surfaces – No smoking.

Keep container tightly closed.

Use explosion-proof electrical, ventilating and light equipment.

Take precautionary measures against static discharge.

Avoid breathing vapors.

Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Wear eye protection.

Response:



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IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

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 attention.

In case of fire: Use water spray or fog, alcohol-resistant foam, carbon dioxide or dry chemical to extinguish.

Storage

Store in a well ventilated place. Keep cool.

Disposal

Dispose of contents and container in accordance with local and national regulations.

Other hazards: None

Section 3. Composition/Information On Ingredients

Component	CAS No.	Amount
Water	7732-18-5	70-80%
Isopropanol	67-63-0	17.2%
Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	111-76-2	1-5%
Diisobutylphenoxyethoxyethyldimethylbenzyl ammonium chloride	121-54-0	0.28%

Section 4. First Aid Measures

Inhalation: Move to fresh air if effects occur and seek medical attention if effects persist.

Skin Contact: Remove contaminated clothing. Wash all affected and exposed areas with soap and water. If skin irritation or redness develops and persists, seek medical attention.

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. Call a poison control center or doctor for treatment advice.

Ingestion: If swallowed, get medical advice by calling a Poison Control Center or hospital emergency room. If advice is not available, take victim and product container to the nearest emergency treatment center or hospital. Do not attempt to give anything by mouth to an unconscious person.

Most Important symptoms and effects, both acute and delayed: Causes serious eye irritation. Inhalation of concentrated vapors may cause irritation of the eyes, nose and throat and dizziness and drowsiness.

Indication of any immediate medical attention and special treatment needed: Immediate medical attention is not generally required.



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Section 5. Fire Fighting Measures

Suitable (and Unsuitable) Extinguishing Media: Use water spray or fog, alcohol-resistant foam, carbon dioxide or dry chemical. Cool fire exposed containers with water.

Specific Hazards Arising from the Chemical: Flammable liquid and vapor. May form explosive mixtures in air at temperatures at or above the flashpoint. Flammable vapors may collect in confined areas. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flashback. Fire exposed containers may rupture explosively.

Special Protective Equipment and Precautions for Fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored.

Section 6: Accidental Release Measures

Personal precautions, Protective equipment, and Emergency procedures: Wear appropriate protective clothing and equipment.

Environmental Precautions: Avoid release to the environment.

Methods and Materials for Containment and Cleaning up: Eliminate all ignition sources. Ventilate area. Use explosion-proof equipment if large amounts are released. Stop leak if it is safe to do so and move containers from the spill area. Collect material with an inert absorbent material and place in appropriate, labeled container for disposal.

Section 7. Handling and Storage

Precautions for Safe Handling: Do not get in eyes or on clothing. Wear appropriate eye protection when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Flammable liquid and vapor. Keep away from heat, sparks, open flames and all other sources of ignition.

Do not smoke in storage or use areas. Keep containers closed when not in use. Do not reuse empty containers.

Conditions for Safe Storage, Including any Incompatibilities: Store in a cool, well ventilated area away from heat, oxidizers and all sources of ignition. Do not contaminate water, food or feed by storage.

Empty containers retain product residues and may be hazardous. Do not flame cut, drill, weld, etc. on or near empty containers, even empty.



CaviCide™
Date Prepared: 3/23/16

Section 8. Exposure Controls / Personal Protection

Exposure Limits

Chemical	Exposure Limit
Water	None Established
Isopropanol	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL
Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	20 ppm TWA ACGIH TLV 50 ppm TWA OSHA PEL (skin)
Diisobutylphenoxyethoxyethyl dimethyl benzylammonium chloride	None Established

Appropriate Engineering Controls: General ventilation should be adequate for normal use. For operations where the exposure limits may be exceeded, mechanical ventilation such as local exhaust may be needed to minimize exposure. Use explosion proof electrical equipment and wiring where required.

Respiratory Protection: None under normal use conditions with adequate ventilation. For operations where the occupational exposure limits are exceeded, an approved respirator with an organic vapor cartridge or supplied air respirator is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with applicable regulations and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

Hand protection: Impervious gloves such as butyl rubber or nitrile are recommended for operations which may result in prolonged or repeated skin contact.

Eye Protection: Splash proof goggles, face shield, or safety glasses are recommended to prevent eye contact.

Skin Protection: Wear protective clothing if needed to avoid prolonged/ repeated skin contact. Contaminated clothing should be removed and laundered before re-use.

Hygiene measures: Suitable eye wash and washing facilities should be available in the work area.

Section 9. Physical and Chemical Properties

Appearance:	Clear liquid.	Odor:	Alcohol
Odor Threshold:	0.001 ppm (ethylene glycol monobutyl ether)	pH:	11.0-12.49
Melting/Freezing Point:	Not determined	Boiling Point/Range:	Not determined
Flash Point:	28.3°C (83°F)	Evaporation Rate:	Not determined
Flammability: (Solid, Gas)	Not applicable	Flammability Limits:	LEL: 2% UEL: 12.7%
Vapor Pressure:	43.3 mmHg @ 20°C (isopropanol)	Vapor Density:	2.1 (isopropanol)
Relative Density:	0.972	Solubilities:	Completely soluble in water



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Partition Coefficient: (N-Octanol/Water)	Not determined	Autoignition Temperature:	Not determined
Decomposition Temperature:	Not determined	Viscosity:	Not determined

Section 10. Stability and Reactivity

Reactivity: Not reactive at ambient temperatures.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Not reactive.

Conditions to avoid: Heat, sparks, flames and all other sources of ignition.

Incompatible Materials: Strong oxidizing agents, acids and strong reducing agents.

Hazardous decomposition products: Thermal decomposition will produce carbon monoxide, carbon dioxide, nitrogen oxides, amines, chlorine and hydrogen chloride.

Section 11. Toxicological Information

Potential Health Effects:

Inhalation: May cause irritation of the nose, throat and upper respiratory tract. High vapor concentrations may produce nausea, vomiting, headache, dizziness, drowsiness, weakness, fatigue, narcosis and possible unconsciousness. Not acutely toxic in rats.

Skin Contact: Prolonged or repeated exposure may cause mild irritation. No signs of toxicity or irritation were observed in a dermal toxicity study in rabbits. Non-irritating in a primary irritation study with rabbits. Negative in a skin sensitization study with guinea pigs.

Eye Contact: May cause irritation with tearing, redness and pain. Moderate irritant in an eye irritation study with rabbits. Effects reversed in 7 days.

Ingestion: Ingestion may cause gastrointestinal disturbances and central nervous system effects such as headache, dizziness, drowsiness and nausea. Not acutely toxic in rats.

Chronic Hazards: Prolonged overexposure to ethylene glycol monobutyl ether may affect liver, kidneys, blood, lymphatic system or central nervous system.

Medical Conditions Aggravated By Exposure: None currently known.

Carcinogen: None of the components is listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA.

Acute Toxicity Values for CaviCide:

LD50 Oral Rat >5000 mg/kg, LD50 Dermal Rat >2000 mg/kg, LC50 inhalation LC50 rat >2.08 mg/L

Section 12. Ecological Information



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This product is not classified as aquatically toxic based on the GHS criteria for aquatic toxicity.

Toxicity: No toxicity data available for product.

Isopropanol: LC50 fathead minnows 11,130 mg/L/48 hr; LC50 brown shrimp 1400 mg/L/48 hr

Diisobutylphenoxyethoxyethyltrimethylbenzylammonium chloride: LC50 pimephales promelas 1.6 mg/L/96 hr, LC50 lepomis macrochirus 1.4 mg/L/96 hr.

Persistence and degradability: Isopropanol and 2-butoxyethanol are readily biodegradable in screening tests. Diisobutylphenoxyethoxyethyltrimethylbenzylammonium chloride is not readily biodegradable.

Bioaccumulative Potential: Isopropanol has an estimated BCF of 3 suggesting that the potential for bioaccumulation is low.

Mobility in Soil: Isopropanol is expected to have very high mobility in soil.

Other Adverse Effects: None known

Section 13. Disposal Considerations

Solution Disposal: Discharge residual and unused solutions in accordance with Federal, State, and local regulations. For used solution, the waste solution must be characterized by the generator and disposed of in accordance with Federal, State, and local regulations.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is not available, discard in accordance with hospital policy.

Section 14. Transport Information

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
US DOT	None	Not Regulated per alcohol exception (49CFR 173.150(e))	None	None	None
EU ADR/RID	UN1987	Alcohols, n.o.s. (Isopropanol)	3	III	None
IMDG	UN1987	Alcohols, n.o.s. (Isopropanol)	3	III	None
IATA/ICAO	UN1987	Alcohols, n.o.s. (Isopropanol)	3	III	None

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None identified

Section 15. Regulatory Information



CaviCide™
Date Prepared: 3/23/16

U.S. Federal Regulations:

EPA SARA 311/312 Hazard Classification: Fire Hazard, Acute Health, Chronic Health

EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372):

Ethylene Glycol Monobutyl Ether (Glycol Ether)	111-76-2	1-5%

Protection Of Stratospheric Ozone: This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A.

CERCLA SECTION 103: This product is not subject to CERCLA reporting requirements; however, many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

US EPA Registered Pesticide: 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!

Harmful if absorbed through the skin.

Causes moderate eye irritation.

Keep out of reach of children.

International Inventories

US EPA TSCA Inventory: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt.

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL) or exempt.

Australia: All of the components in this product are listed on the Australian Inventory of Chemical Substances (AICS) or exempt.

China: All of the components in this product are listed on the Inventory of Existing Chemical Substances in China (IECSC) or exempt.

European Union: All the components in this product are listed on the EINECS inventory or exempt.

Japan: All of the components in this product are listed on the Japanese Existing and New Chemical Substances (ENCS) inventory or exempt.

Korea: All of the components in this product are listed on the Korean Existing Chemicals List (KECL) or



CaviCide™
Date Prepared: 3/23/16

exempt.

Philippines: All of the components of this product are listed on the Philippines Inventory of Chemicals and Chemical Substances (PICCS) or exempt.

Section 16. Other Information

Effective Date: March 23, 2016

Supersedes Date: June 1, 2015

Revision Summary: Removed prop 65 notice per exposure assessment.

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date of preparation, however, METREX™ RESEARCH makes no warranty with respect to the accuracy or suitability of the recommendations, and assumes no liability to any use thereof.



PRODUCT SAFETY DATA SUMMARY

UCB Pharma SA / NV, Allée de la Recherche, 60, B-1070, Brussels, Belgium.

For further information, contact corporatehse@ucb.com

This Product Safety Data Summary Sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information to medicinal use of the product for the patients. For this instance the prescribing information should be consulted.

For health and safety information for individual ingredients used, refer to the appropriate Safety Data Sheet for each ingredient.

IDENTIFICATION AND COMPOSITION OF THE SUBSTANCE/PREPARATION

Product Name:	Certolizumab pegol – Lyophilized powder for solution
Other Name:	Cimzia
Appearance:	Each single-use vial of CIMZIA contains approximately 200 mg certolizumab pegol. After reconstitution, each vial contains 200 mg per ml of certolizumab pegol.
Use:	Medicinal Product. Certolizumab pegol is a recombinant humanized antibody Fab' fragment that is expressed in an Escherichia coli bacterial expression system, subsequently purified and conjugated to polyethylene glycol (PEG). Used in the treatment of Crohn's disease, rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis

HAZARD IDENTIFICATION

Classification according to Directive 67/548/ECC or 1999/45/EC as amended and Regulation (EC) N°1272/2008 as amended: product regulated as a medicinal product.

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.

In the case of accidental exposure to the product or if you feel unwell, seek medical advice immediately and show the label where possible.

Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

FIRST AID MEASURES

Inhalation:	Move to fresh air. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Ingestion:	If swallowed, wash out mouth with water (only if the person is conscious). Obtain medical attention.
Skin Contact:	Remove contaminated clothing. Immediately flush skin with plenty of water. Get medical attention if symptoms occur.
Eye Contact:	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

FIRE

No unusual fire or explosion hazards noted.

May give off toxic fumes. Use the extinguishing media recommended for the primary cause of fire.

ACCIDENTAL RELEASE MEASURES

Keep unnecessary personnel away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Avoid release to the environment. Avoid discharge into drains, water courses or onto the ground.

Spilled product should be swept up or absorbed onto absorbent material and the area washed with water and detergent.

HANDLING, STORAGE AND DISPOSAL CONSIDERATIONS

Store at 2°C – 8°C (in a refrigerator)

Do not freeze.

Observe all local and national regulations when disposing of the material. Treat as hazardous waste.

EXPOSURE CONTROLS/PERSONAL PROTECTION

General ventilation normally adequate. Gloves should be worn at all times when handling the material.

Always observe good personal hygiene measures, such as washing after handling the material and before eating and drinking. Routinely wash work clothing and protective equipment to remove potential contaminants.

TRANSPORT INFORMATION

Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

REGULATORY INFORMATION

The packed finished product intended for the final user is exempt from classification under EC requirements.

OTHER INFORMATION

This data summary replaces all earlier versions.

Since the use of this information and the product are not within the control of UCB, it is the user's responsibility to determine the conditions of safe use of the product.

Date originated/reviewed: 13/01/2016.



SAFETY DATA SHEET

Issuing Date 10-Jan-2017

Revision Date 15-Aug-2017

Revision Number 3

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Clorox Healthcare® Bleach Germicidal Wipes

Other means of identification

Synonyms None

EPA Pesticide registration number 67619-12

Recommended use of the chemical and restrictions on use

Recommended Use Wipes, Disinfecting

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier The Clorox Company

Supplier Address 1221 Broadway
Oakland
CA
94612
US

Telephone 1-510-271-7000

Emergency telephone number

Emergency Telephone Number For Medical Emergencies call: 1-800-446-1014. 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

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance White

Physical state
Pre-Moistened Towelette
(no free liquids)

Odor Fruity, Floral, Bleach

Precautionary Statements - Prevention

Not applicable

Precautionary Statements - Response

None

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

21.8 % of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals

No information available.

Interactions with Other Chemicals

May react with bleach-containing products or other household cleaners to produce hazardous gases.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The product contains no substances which at their given concentration, 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

Rinse thoroughly with water as necessary. If symptoms persist, call a physician.

Skin contact

Wash with soap and water. If skin irritation persists, call a physician.

Inhalation

Remove to fresh air. If breathing is difficult, (trained personnel should) give oxygen. If symptoms persist, call a physician.

Ingestion

Drink 1 or 2 glasses of water. Get medical attention if symptoms occur.

Most important symptoms and effects, both acute and delayed**Most Important Symptoms and Effects**

Irritating.

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.

Hazardous Combustion Products

Carbon oxides.

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 Pick up and transfer to properly labeled containers.

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 None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

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

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures 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 exposure limits are exceeded or 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	Pre-Moistened Towelette (no free liquids)		
Appearance	White	Odor	Fruity Floral Bleach
Color	No information available	Odor Threshold	No information available
Property	Values	Remarks	Method
pH	12 - 12.5 (liquid)	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 Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	~1.0 (liquid)	None known	
Water Solubility	Completely soluble	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	0	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	No data available		
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 under normal processing.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Ammonia Acids

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Product Information**

Inhalation	May cause irritation of respiratory tract.
Eye contact	May cause slight irritation.
Skin contact	Substance may cause slight skin irritation.
Ingestion	Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information**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.

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

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 No known effect based on information supplied.

Target Organ Effects Eyes. Skin. Respiratory system. Reproductive system.

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

No information available

12. ECOLOGICAL INFORMATION**Ecotoxicity**

None known.

Persistence and Degradability

No information available.

Bioaccumulation

No information available

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods****Disposal methods**

Dispose of in accordance with federal, state and local regulations.

Contaminated Packaging

Do not reuse empty containers. Dispose of in accordance with 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****International Inventories**

TSCA

All components are listed on the TSCA Inventory

DSL

All components are listed either 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**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

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 does not contain any substances above threshold limits that are regulated by state right-to-know.

EPA Pesticide registration number 67619-12

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:

EPA Pesticide label

CAUTION: Liquid causes moderate eye irritation. Do not get in eyes or on clothing. Avoid contact with clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. For sensitive skin or prolonged use, wear gloves.

International Regulations

Canada

WHMIS Hazard Class

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards 1	Flammability 0	Instability 1	Physical and Chemical Hazards
HMIS	Health Hazards 1	Flammability 0	Physical Hazard 1	N/A
				Personal Protection
				A

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
Issuing Date	10-Jan-2017
Revision Date	15-Aug-2017
Revision Note	No information available

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 No data available

Revision Date 25-Aug-2017

Revision Number 6

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes

Other means of identification

Synonyms None

EPA Pesticide registration number 67619-25

Recommended use of the chemical and restrictions on use

Recommended Use Wipes, Disinfecting

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier The Clorox Company

Supplier Address 1221 Broadway
Oakland
CA
94612
US

Telephone 1-510-271-7000

Emergency telephone number

Emergency Telephone Number For Medical Emergencies call: 1-800-446-1014. 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

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance White

Physical state
Pre-Moistened Towelette
(no free liquids)

Odor Cleaning Agent

Precautionary Statements - Prevention

Not applicable

Precautionary Statements - Response

None

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

19 % of the mixture consists of ingredient(s) of unknown toxicity

Other information

Harmful to aquatic life with long lasting effects

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The product contains no substances which at their given concentration, 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

Rinse thoroughly with water as necessary. Get medical attention if irritation develops and persists.

Skin contact

Wash skin with soap and water. Get medical attention if irritation develops and persists.

Inhalation

If symptoms develop move victim to fresh air. If breathing is difficult, (trained personnel should) give oxygen. If symptoms persist, call a physician.

Ingestion

Drink 1 or 2 glasses of water. Get medical attention if symptoms occur.

Self-protection of the first aider

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Most important symptoms and effects, both acute and delayed**Most Important Symptoms and Effects**

None known.

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.

Hazardous Combustion Products

Carbon oxides.

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 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 None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Appropriate engineering controls

Engineering Measures 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 exposure limits are exceeded or 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	Pre-Moistened Towelette (no free liquids)		
Appearance	White	Odor	Cleaning Agent
Color	No information available	Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	2 - 3 (liquid)	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	>93°C	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	~1.0 (liquid)	None known	
Water Solubility	Completely soluble	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	0	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	No data available		
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 under normal processing.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known

Hazardous Decomposition Products

None known.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Product Information**

Inhalation	May cause irritation of respiratory tract.
Eye contact	May cause slight irritation.
Skin contact	Substance may cause slight skin irritation.
Ingestion	Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information**Information on toxicological effects**

Symptoms No information available.

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 There are no known carcinogenic chemicals in this product.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity No known effect based on information supplied.

Target Organ Effects No information available.

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

No information available

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Harmful 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**Waste treatment methods****Disposal methods**

Dispose of in accordance with federal, state and local regulations.

Contaminated Packaging

Do not reuse empty containers. Dispose of in accordance with 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**International Inventories**

TSCA

All components are listed on the TSCA Inventory

DSL

All components are listed either 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**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

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 does not contain any substances above threshold limits that are regulated by state right-to-know.

EPA Pesticide registration number 67619-25

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:

EPA Pesticide label

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

International Regulations**Mexico****National occupational exposure limits**

No data available

Canada**WHMIS Hazard Class**

Non-controlled

16. OTHER INFORMATION				

NFPA	Health Hazards	1	Flammability	0	Instability	0	Physical and Chemical Hazards	-
HMIS	Health Hazards	1	Flammability	0	Physical Hazard	0	Personal Protection	A

Prepared By

Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Revision Date

25-Aug-2017

Revision Note

No information available

Reference

1138497/164708.001

Disclaimer

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End of Safety Data Sheet

Safety Data Sheet for Drug product



Date of issue: 16-JAN-2017

Replaces version of: 17-MAY-2016

COSENTYX SYRINGE 150MG/ML SENSOREADYPEN 888090 (MARS)

1. Identification of the substance/preparation and of the company

Product name	COSENTYX SYRINGE 150MG/ML SENSOREADYPEN
Chemical Class	Human monoclonal antibody
Generic Name	AIN457-NXA, aqueous solution
Pharmacological Action	antirheumatic, antiphlogistic, psoriasis treatment, Immunomodulator, Human monoclonal antibody
Usage	no data available
Company name	NIBR East Hanover One Health Plaza East Hanover, NJ 07936 sds.support@novartis.com
Emergency phone number	CHEMTEL (US/Canada) 1-800-255-3924

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:
AIN457-NXA, aqueous solution	2.4 - 15 %

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

4. First aid measures

Eye Contact	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation	Remove the victim from danger zone, avoid further exposure.
Ingestion	If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician	General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media	Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media	No restrictions
Dangerous Combustion Products	None, when used and handled as intended.
Protective equipment for firefighters	Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions	Avoid contact with skin, eyes and clothing.
Environmental	Must not be released into sewers, drains or wells.

Safety Data Sheet for Drug product



Date of issue: 16-JAN-2017

Replaces version of: 17-MAY-2016

COSENTYX SYRINGE 150MG/ML SENSOREADYPEN 888090 (MARS)

precautions

Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components

Contains:

AIN457-NXA, aqueous solution

List type	Value	Unit	
Internal exposure limit	350	µg/m3	HHA Database

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Formulation Injection solution in ampul

Flash Point not applicable

10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity no data available

Irritation, Corrosion no data available

Sensitisation no data available

Mutagenicity no data available

Chronic Effects

Data of AIN457-NXA, aqueous solution

No pathological findings (Repeated Dose Toxicity)

NOAEL: 100 mg/kg/w

Route: intravenous

Species: cynomolgus monkey (Macaca fascicularis), Organ: No target organ of toxicity

Dosage: <= 100 mg/kg/w, Duration: 4 weeks

Data of AIN457-NXA, aqueous solution

No pathological findings (Repeated Dose Toxicity)

NOAEL: 150 mg/kg/w

Route: intravenous

Species: cynomolgus monkey (Macaca fascicularis), Organ: No target organ of toxicity

Dosage: <= 150 mg/kg/w, Duration: 4 weeks

Data of AIN457-NXA, aqueous solution

(Repeated Dose Toxicity)

NOAEL: 150 mg/kg/w

Route: intravenous

Safety Data Sheet for Drug product



Date of issue: 16-JAN-2017

Replaces version of: 17-MAY-2016

COSENTYX SYRINGE 150MG/ML SENSOREADYPEN 888090 (MARS)

	Species: cynomolgus monkey (Macaca fascicularis), Organ: Immune system
	Dosage: <= 150 mg/kg/w, Duration: 26 weeks
Reproduction Toxicity	Data of AIN457-NXA, aqueous solution
	Not teratogenic / not embryotoxic (Embryo-Fetal Development)
	NOAEL: 150 mg/kg/w
	Route: subcutaneous
	Species: cynomolgus monkey (Macaca fascicularis)
	Data of AIN457-NXA, aqueous solution
	Negative (Peri- and Postnatal Development)
	NOAEL: 150 mg/kg/w
	Route: subcutaneous
	Species: mouse

12. Ecological information

Biological Elimination	no data available
Fish acute toxicity	no data available
Aquatic invertebrate acute toxicity	no data available
Algae Toxicity	no data available
Bacterial Respiration Inhibition	no data available
Ecotoxicity Summary	Data of AIN457-NXA, aqueous solution Based on the present knowledge, this product is to be classified as non-hazardous for the environment.

13. Disposal considerations

Disposal Requirements	Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

ICAO/IATA-DGR: no dangerous good
Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:
AIN457-NXA, aqueous solution	2.4 - 15 %

Remaining components are inert ingredients.

16. Other information

Abbreviations used

Recipient 3E Company

Safety Data Sheet for Drug product



Date of issue: 16-JAN-2017

Replaces version of: 17-MAY-2016

COSENTYX SYRINGE 150MG/ML SENSOREADYPEN 888090 (MARS)

Supplier Relations
3207 Grey Hawk Court
Carlsbad, CA
USA

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Cyanocobalamin Injection, USP

Section 1. Identification

GHS product identifier	: Cyanocobalamin Injection, USP
Synonyms	: Not available.
Product code	: NDC 0143-9621-25 (25 x 1 mL vials), NDC 0143-9620-10 (10 x 10 mL vials), NDC 0143-9619-10 (10 x 30 mL vials)
Chemical family	: Not available.
Product type	: Not available.
Container information	: (2 ml Vial, amps etc) 2 mL amber glass vial, 10 mL amber glass vial, 30 mL amber glass vial.
Identified uses	: Cyanocobalamin is indicated for vitamin B12 deficiencies due to malabsorption which may be associated with the following conditions: Addisonian (pernicious) anemia Gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacteria overgrowth, total or partial gastrectomy Fish tapeworm infestation Malignancy of pancreas or bowel Folic acid deficiency It may be possible to treat the underlying disease by surgical correction of anatomic lesions leading to small bowel bacterial overgrowth, expulsion of fish tapeworm, discontinuation of drugs leading to vitamin malabsorption, use of a gluten-free diet in nontropical sprue, or administration of antibiotics in tropical sprue. Such measures remove the need for long-term administration of cyanocobalamin. Requirements of vitamin B12 in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation. Cyanocobalamin Injection, USP is also suitable for the vitamin B12 absorption test (Schilling test).
Supplier's details	: West-Ward Pharmaceuticals Corp. 465 Industrial Way West Eatontown NJ 07724 USA
Emergency telephone number (with hours of operation)	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

Section 2. Hazards identification

OSHA/HCS status	: While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
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.



KMK Regulatory Services

Tel : +1-888-GHS-7769 (447-7769) / +1-450-GHS-7767 (447-7767)
 www.kmkregservices.com www.askdrluc.com www.ghssmart.com



Section 2. Hazards identification

Precautionary statements

- Prevention** : Not applicable.
- Response** : Not applicable.
- Storage** : Not applicable.
- Disposal** : Not applicable.
- Hazards not otherwise classified** : None known.
- Hazards not otherwise classified (HNOC)** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Not available.

CAS number/other identifiers

- CAS number** : Not applicable.
- Product code** : NDC 0143-9621-25 (25 x 1 mL vials), NDC 0143-9620-10 (10 x 10 mL vials), NDC 0143-9619-10 (10 x 30 mL vials)

Ingredient name	%	CAS number
Water	90 - 100	7732-18-5
Benzyl alcohol	1 - 3	100-51-6
Sodium chloride	0.3 - 1	7647-14-5
Sodium hydroxide	0 - 0.1	1310-73-2
Hydrochloric acid	0 - 0.1	7647-01-0
Cyanocobalamin	0 - 0.1	68-19-9

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. 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.





Section 4. First aid measures

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

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.

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 : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

Special protective actions for fire-fighters : No special measures are required.

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. 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 specialized 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





Section 6. Accidental release measures

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. 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. 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. 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

Ingredient name	Exposure limits
Benzyl alcohol	AIHA WEEL (United States, 10/2011). TWA: 10 ppm 8 hours.

- 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.

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.
- 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





Section 8. Exposure controls/personal 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	: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state	: Liquid.
Color	: Clear. Red.
Odor	: Not available.
Odor threshold	: Not available.
pH	: 4.5 to 7
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition 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.





Section 10. Stability and reactivity

Incompatible materials : Not available.

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

Product/ingredient name	Result	Species	Dose	Exposure
Benzyl alcohol	LD50 Dermal	Rabbit	2000 mg/kg	-
	LD50 Oral	Rat	1230 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Benzyl alcohol	Skin - Mild irritant	Man	-	48 hours 16 mg	-
	Skin - Moderate irritant	Pig	-	100 %	-
	Skin - Moderate irritant	Rabbit	-	24 hours 100 mg	-

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

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 known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.





Section 11. Toxicological information

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

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

Route	ATE value
Oral	82000 mg/kg
Inhalation (vapors)	733.3 mg/L

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Benzyl alcohol	Acute LC50 460000 µg/L Fresh water	Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling)	96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Benzyl alcohol	0.87	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.





Cyanocobalamin Injection, USP

Section 12. Ecological information

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 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	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

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 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): All components are listed or exempted.
Clean Water Act (CWA) 311: Sodium hydroxide; Hydrochloric acid

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed





Cyanocobalamin Injection, USP

Section 15. Regulatory information

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

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.1	Yes.	500	-	5000	-

SARA 304 RQ : 50000000 lbs / 22700000 kg [5982944.8 gal / 22647909.8 L]

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Benzyl alcohol	≥1 - ≤3	No.	No.	No.	Yes.	No.

SARA 313

	Product name	CAS number	%
Form R - Reporting requirements	Cyanocobalamin	68-19-9	≤0.3
Supplier notification	Cyanocobalamin	68-19-9	≤0.3

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

Massachusetts : The following components are listed: Benzyl alcohol

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: Benzyl alcohol

California Prop. 65

No products were found.





Section 16. Other information

History

Date of issue mm/dd/yyyy : 03/15/2016

Version : 1

Prepared by : KMK Regulatory Services Inc.

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 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
 UN = United Nations

Notice to reader

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.





SAFETY DATA SHEET

Revision date: 23-Mar-2017

Version: 3.1

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Methylprednisolone Acetate Suspension, USP, Sterile

Trade Name: Depo-Medrol
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
 235 East 42nd Street
 New York, New York 10017
 1-800-879-3477

Pfizer Ltd
 Ramsgate Road
 Sandwich, Kent
 CT13 9NJ
 United Kingdom
 +00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
 Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
 H373 - May cause damage to organs through prolonged or repeated exposure if swallowed

Precautionary Statements: P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 P281 - Use personal protective equipment as required
 P308 + P313 - IF exposed or concerned: Get medical attention/advice
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P314 - Get medical attention/advice if you feel unwell
 P405 - Store locked up
 P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 23-Mar-2017

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**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0
Methylprednisolone Acetate	53-36-1	200-171-3	Repr.1A (H360D) STOT RE.2 (H373)	2-8

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	500-019-9	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES**Description of First Aid Measures****Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 23-Mar-2017

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Version: 3.1

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: May include oxides of carbon.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE**Precautions for Safe Handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control Parameters**

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 23-Mar-2017

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Methylprednisolone Acetate

Pfizer OEL TWA-8 Hr: 4µg/m³, Skin

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL - TWAs	1000 mg/m ³

Sodium phosphate, dibasic

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium phosphate, monobasic

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Suspension	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Methylprednisolone Acetate

No data available

Methylprednisolone

Predicted 7.4 Log D 1.99

Water

No data available

Polyethylene glycol

No data available

Polysorbate 80

No data available

Sodium phosphate, dibasic

No data available

Sodium phosphate, monobasic

No data available

Benzyl Alcohol

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization:

Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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10. STABILITY AND REACTIVITY

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION**Information on Toxicological Effects****General Information:**

The information included in this section describes the potential hazards of the individual ingredients. The information included in this section describes the potential hazards of various forms of the active ingredient.

Short Term:

May be harmful if absorbed through the skin. Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. May produce allergic reactions following skin contact.

Long Term:

Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.

Known Clinical Effects:

Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use has resulted in hormonal alterations. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes.

Acute Toxicity: (Species, Route, End Point, Dose)**Methylprednisolone Acetate**

Rat Oral LD50 >10,000 mg/kg
Mouse Sub-tenon injection (eye) LD50 >1,409mg/kg
Rat Subcutaneous LD50 265mg/kg

Methylprednisolone

Rat Oral LD 50 > 2000 mg/kg
Mouse Oral LD 50 450mg/kg
Rat Intraperitoneal LD 50 1000mg/kg
Mouse Intraperitoneal LD 50 1409mg/kg
Rat Subcutaneous LD 50 >3000mg/kg

Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/L

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)**Methylprednisolone Acetate**

Eye Irritation Rabbit No effect
Skin Irritation Rabbit No effect

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11. TOXICOLOGICAL INFORMATION**Methylprednisolone**

Skin Irritation Rabbit No effect
Eye Irritation Rabbit No effect
Skin Sensitization - GPMT Guinea Pig No effect

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Benzyl Alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Methylprednisolone**

42 Day(s)	Dog	Oral	167 µg/kg/day	LOAEL	Adrenal gland
6 Week(s)	Rat	Subcutaneous	500 µg/kg/day	LOAEL	None identified
14 Week(s)	Rat	Subcutaneous	0.4 µg/kg/day	NOAEL	Blood forming organs, Adrenal gland
52 Week(s)	Rat	Subcutaneous	4 µg/kg/day	NOAEL	Blood forming organs Adrenal gland

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**Methylprednisolone**

Reproductive & Fertility	Rat	Subcutaneous	0.004 mg/kg/day	NOAEL	Paternal toxicity
Reproductive & Fertility	Rat	Subcutaneous	0.02 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	1.0 mg/kg/day	LOAEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Intramuscular	330 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.1 mg/kg/day	LOAEL	Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Methylprednisolone Acetate**

Direct DNA Interaction Not applicable Negative
In Vitro Cytogenetics Not applicable Negative

Methylprednisolone

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis Rat Hepatocyte Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
Direct DNA Interaction Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)****Benzyl Alcohol**

Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 460 mg/L

Daphnia magna (Water Flea) OECD EC50 48 Hours 230 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 500 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**Benzyl Alcohol**

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability:**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)****Benzyl Alcohol**

OECD Activated sludge Ready 92% After 14 Day(s) Ready

Bio-accumulative Potential: No data available

Partition Coefficient: (Method, pH, Endpoint, Value)**Methylprednisolone**

Predicted 7.4 Log D 1.99

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Methylprednisolone Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	200-171-3

Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	500-019-9

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-449-2

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15. REGULATORY INFORMATION**Water**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Reproductive toxicity-Cat. 1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure if swallowed
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 2 - Hazard Identification.

Revision date: 23-Mar-2017
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

hikma.

Diphenhydramine Hydrochloride Injection, USP

Section 1. Identification

GHS product identifier : Diphenhydramine Hydrochloride Injection, USP**Synonyms** : None.**Product code** : Not available.**Chemical family** : Antihistaminic agent.**Product type** : Regulated prescription drug.**Container information** : 1 mL vials.**Relevant identified uses of the substance or mixture and uses advised against**

Pharmaceuticals.

Supplier's details : Hikma Pharmaceuticals USA Inc.
246 Industrial Way West
Eatontown, New Jersey (NJ) 07724**Emergency telephone number (with hours of operation)** : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3877

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.**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**Other means of identification** : None.**CAS number/other identifiers**

hikma.**Diphenhydramine Hydrochloride Injection, USP****Section 3. Composition/information on ingredients**

Ingredient name	%	CAS number
Water	60 - 100	7732-18-5
Diphenhydramine Hydrochloride	1 - 5	147-24-0
Benzethonium Chloride	0 - 0.1	121-54-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional 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. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. 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** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- 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.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- 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 measuresExtinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds

Special protective actions for fire-fighters : No special protection is required.

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 measuresPersonal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. 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 specialized 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

Spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. 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. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storagePrecautions 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. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

Section 7. Handling and storage

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 : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

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. Ensure that eyewash stations and safety showers are close to the workstation location.

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, air-purifying or supplied air 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

Appearance

Physical state	: Liquid. [Aqueous solution.]
Color	: Colorless.
Odor	: Not available.
Odor threshold	: Not available.
pH	: 4 to 6.5
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not applicable.
Burning time	: Not applicable.
Burning rate	: Not applicable.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Not available.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
SADT	: 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	: Reactive or incompatible with the following materials: oxidizing materials and acids.
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**

Product/ingredient name	Result	Species	Dose	Exposure
Diphenhydramine Hydrochloride	LD50 Oral	Rat	500 mg/kg	-

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- 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 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.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Long term exposure



Section 11. Toxicological information

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

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

Route	ATE value
Oral	10000 mg/kg

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data 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 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.



Diphenhydramine Hydrochloride Injection, USP

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

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 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



Diphenhydramine Hydrochloride Injection, USP

Section 15. Regulatory information

Classification : Not applicable.

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Diphenhydramine Hydrochloride	1 - 5	No.	No.	No.	Yes.	No.

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

No products were found.

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: Not determined.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Revision date mm/dd/yyyy : 12/15/2018

Version : 2

Prepared by : KMK Regulatory Services Inc.

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)



Diphenhydramine Hydrochloride Injection, USP

Section 16. Other information

UN = United Nations

Notice to reader

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.



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Enbrel[®]

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

1.1 Product identifier

Product Name: Enbrel
Common Name: etanercept
Chemical Name: Not Applicable
Synonyms: Recombinant human tumor necrosis factor receptor p75:Fc; rhuTNFR:Fc; etanercept

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

Recommended Use: Pharmaceutical
Uses advised against: No information available

Manufacturer:

Amgen Inc.
 One Amgen Center Drive
 Thousand Oaks, California 91320-1799
 1-805-447-7233
 1-805-447-1000

Emergency Telephone Number:

Chemtrec
 NORTH AMERICA 1-800-424-9300,
 INTERNATIONAL 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains etanercept (recombinant human tumor necrosis factor receptor:Fc), an active pharmaceutical ingredient for inflammatory and immune diseases. Dosage form contents may pose a health hazard only if significant absorption occurs (e.g., inhalation after major spill or leak). May increase frequency of infections and autoantibody formation. Avoid inhalation, skin contact, eye contact, and accidental ingestion. Does not meet GHS classification criteria and therefore is not classified.

2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Not classified

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

2.2 Label elements

Not classified



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2.3 Other Hazards No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredients: Proprietary information**Chemical Name:** Not Applicable**CAS-No:** 185243-69-0

Single-use prefilled syringes containing 25 mg (0.51 mL of a 50 mg/mL solution of etanercept) and 50 mg (0.98 mL of a 50 mg/mL solution of etanercept) dosage strengths. Single-use prefilled Sureclick[®] autoinjector containing 50 mg (0.98 mL of a 50 mg/mL solution of etanercept). Each prefilled syringe and SureClick[®] autoinjector contains a 50 mg/mL solution of etanercept with:

	CAS Number:	Amount
Sucrose	57-50-1	10 mg/mL
Sodium chloride (NaCl)	7647-14-5	5.8 mg/mL
L-Arginine hydrochloride	15595-35-4	5.3 mg/mL
Sodium phosphate monobasic monohydrate	7558-80-7	2.6 mg/mL
Sodium phosphate dibasic anhydrous	7558-79-4	0.9 mg/mL

Multi-use vials containing 25 mg etanercept with:

	CAS Number:	Amount
Sucrose	57-50-1	10 mg
Mannitol	87-78-5	40 mg
Tromethamine	108195-86-4	1.2 mg

4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye Contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. If symptoms persist, call a physician.

Ingestion: If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

Notes to Physician: Treat symptomatically.



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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Flammable Properties: Not applicable.

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous Combustion Products: None

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Spill Procedures: If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Handling and Storage: Avoid contact with skin, eyes, or clothing. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 55 µg/m³ as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Enbrel[®] has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m³ - 100 µg/m³).

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

8.2 Exposure controls

Personal Protective Equipment

Eye/face Protection: Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

Respiratory Protection: When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed.

Other: Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

8.3 Environmental exposure controls

Environmental Exposure Controls Avoid release to the environment.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear colorless liquid or white lyophilized powder
Molecular Weight:	Approx. 130,000 Daltons
Odor:	No information available
Odor Threshold:	No information available
pH:	6.3 ± 0.2 (liquid)/ 7.4 ± 0.3 (lyophilized powder)
Melting Point:	No information available
Flash Point:	Not applicable /aqueous solution
Evaporation Rate:	No information available
Lower explosive limit:	No information available
Upper explosive limit:	No information available
Vapor Pressure:	No information available
Vapor Density (air = 1):	No information available
Relative density:	No information available
Water Solubility:	No information available
Partition Coefficient (log Kow):	No information available
Viscosity:	No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity	No information available
10.2 Chemical stability	Stable
10.3 Possibility of hazardous reactions	No information available
10.4 Conditions to avoid	No Information available
10.5 Incompatible materials	No information available
10.6 Hazardous decomposition products	No information available
10.7 Other information	None



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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity:	No information available
Skin corrosion/irritation:	No information available
Serious eye damage/eye irritation:	No information available
Respiratory or skin sensitization:	No information available
Germ cell mutagenicity:	Even though this does not meet GHS classification, the following data is available: Not genotoxic based on a battery of in vitro and in vivo studies.
Carcinogenicity:	No information available
Reproductive toxicity:	Even though this does not meet GHS classification, the following data is available: No increase in birth defects rate in rats or rabbits given doses 60 to 100 times the human dose.
STOT - single exposure:	Even though this does not meet GHS classification, the following data is available: Enbrel [®] was administered and no dose-limiting toxicities were noted in monkeys or healthy volunteers given dose 30 and 4 times, respectively, the human dose. As a glycoprotein, etanercept is expected to be poorly absorbed orally and exhibit low acute oral toxicity if accidentally ingested. Inhalation of aerosol from an acute exposure from a major spill or significant overexposure in manufacturing may cause autoantibody formation or allergies.
STOT - repeated exposure:	Even though this does not meet GHS classification, the following data is available: Enbrel [®] was administered in monkeys twice weekly at doses of 1, 1.5 or 15 mg/kg for 26 weeks. No significant effects were noted. Antibodies noted in all monkeys treated twice weekly for 26 weeks. However, no other adverse effects noted.
Aspiration Hazard:	No information available



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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects: No information available

12.2 Persistence and degradability

Persistence/Degradability: No information available

12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation: No information available

12.4 Mobility in soil

Mobility in Environmental Media: No information available

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

12.6 Other adverse effects

Other Adverse Effects: No information available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Disposal Method: Dispose of any waste according to prescribed federal, state, local and competent authority guidelines.

14. TRANSPORT INFORMATION

DOT Not regulated by U.S. DOT or IATA



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15. REGULATORY INFORMATION

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

International Inventories

TSCA:	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS:	-
ENCS:	-
CHINA:	-
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

State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

15.2 Chemical safety assessment

No CSA has been conducted.



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16. OTHER INFORMATION

Text of R phrases mentioned in Section 2

No information available

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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 and protections, 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 because it may be biologically active.



SAFETY DATA SHEET (SDS)

Section 1: IDENTIFICATION					
TRADE NAME	GEBAUER'S ETHYL CHLORIDE®	MANUFACTURER	Gebauer Company 4444 East 153 Street Cleveland, Ohio 44128		
CHEMICAL NAME	Ethyl Chloride	CONTACT INFORMATION	Toll Free: (800) 321-9348 Phone: (216) 518-3030 Fax: (216) 581-4970		
RECOMMENDED USE	Topical Anesthetic	IN CASE OF EMERGENCY	CHEMTREC - (800) 242-9300 or (703) 527-3887		
FORMULA	C ₂ H ₅ Cl	CHEMICAL FAMILY	Halogenated Hydrocarbon		
Section 2: HAZARDS IDENTIFICATION					
		Health Rating	2 - Moderate		
		Flammability Rating	4 - Acute		
		Reactivity Rating	0 - None		
		Special Rating	None		
		Lab Protective Equipment	Neoprene or Viton gloves, lab coat, goggles or face shield, vent hood.		
		Storage Color Code	Red (Flammable)		
Hazard Category	Signal Word	Hazard Statement	Pictogram	Precautionary Statement	
Flammable Gas (Category 1)	Danger	Extremely flammable gas		Keep away from heat/sparks/open flames/hot surfaces/cautery equipment – No smoking.	
Compressed Gas	Warning	Contains gas under pressure; may explode if heated		Store in a well-ventilated place.	
Eye Irritation (Category 2B)	Warning	Causes eye irritation	N/A	If product gets into eyes, see the Section 4: First Aid Measures.	
Acute Toxicity (Category 4)	Warning	Harmful if inhaled		If inhaled, see the Section 4: First Aid Measures.	
Cause		Effects			
Potential Acute Health Effects		Inhalation	Headache, dizziness, nausea, vomiting, loss of coordination and disorientation may produce narcotic and anesthetic effects. May produce central nervous system depression, respiratory paralysis, or fatal coma with respiratory or cardiac arrest. May sensitize the myocardium to endogenous epinephrine, causing dangerous dysrhythmias. Although absorbed through lungs and skin, it also is rapidly given off through the lungs.		
		Ingestion	Unlikely route of exposure due to gaseous nature.		
		Skin Contact	Rapid evaporation of liquid may cause frostbite. Symptoms of frostbite are blanching of the skin, cold feeling numbness. Cutaneous sensitization may occur, but is extremely rare. Freezing can occasionally alter pigmentation. A single prolonged skin exposure is not likely to result in absorption of harmful amounts		
		Chronic Exposure	Long term exposure to high levels may produce the following: loss of muscle coordination, involuntary eye movements, tremors, speech disturbance, sluggish reflexes and hallucinations. These symptoms are alleviated when the overexposure is ended.		
		Aggravation of Preexisting Conditions	The defatting properties of Ethyl Chloride may aggravate existing dermatitis.		
Section 3: COMPOSITION / INFORMATION ON INGREDIENTS					
Ingredient	Synonyms	CAS Number	Concentration	OSHA PEL	ACGIH TLV-TWA
Ethyl Chloride	Chloroethane, Hydrochloric Ether	75-00-3	>99	1000ppm	100ppm
Section 4: FIRST AID MEASURES					
Inhalation	Immediately remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, qualified personnel may give oxygen. Call a physician.				
Ingestion	Unlikely route of exposure due to gaseous nature.				
Skin Contact	For exposure to liquid, immediately warm frostbite area with warm water not to exceed 105°F (41°C). In case of massive exposure, remove contaminated clothing while showering with warm water. Call a physician.				
Eye Contact	For exposure to liquid, check for and remove any contact lenses. Immediately flush eyes thoroughly with warm water for at least 15 minutes. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly. See a physician, preferably an ophthalmologist, immediately.				

Section 5: FIRE FIGHTING MEASURES

Special Fire Fighting Procedures

DANGER! Flammable liquid and gas. Evacuate all personnel from danger area. Use water spray to cool fire-exposed containers, structures and equipment. Use water spray, carbon dioxide or dry chemicals as extinguishing media. Do not use stream of water because it will scatter and spread the fire. Remove sources of ignition if without risk. Remove all containers from fire area if without risk; continue cooling water spray while moving containers. Do not extinguish any flames emitted from containers, stop flow of material if without risk, or allow flames to burn out. Self contained breathing apparatus may be required by rescue workers.

Unusual Fire and Explosion Hazards

Flammable liquid and gas. Very dangerous fire hazard when exposed to heat, flame or powerful oxidizers. Ethyl chloride is heavier than air and the vapors may hug the ground, making distant ignition and flashback possible. During a fire, toxic gases (hydrogen chloride, chlorine and phosgene) may be produced. Direct exposure to flames may cause container explosion. Static discharge may ignite ethyl chloride.

Section 6: ACCIDENTAL RELEASE MEASURES

Spill and Leak Response

Flammable liquid and Gas. Eliminate all sources of ignition. Allow spilled ethyl chloride to evaporate, ventilate enclosed areas. In case of large spill, evacuate all personnel from area. For Entry Into Unknown Concentrations That Could Be IDLH (≥ 3800 ppm): Full Face Self Contained Breathing Apparatus

Waste Disposal Method

Comply with federal, state and local laws; return unused quantities to Gebauer Company by making appropriate arrangements for pickup and transportation.

Section 7: HANDLING AND STORAGE

Storage Precautions

Store in cool, dry well ventilated area. Protect against physical damage. Do not subject to temperatures above 120°F (50°C). Do not store near high frequency ultrasound equipment or non-explosion proof electrical equipment.

Handling Precautions

Use in well-ventilated areas. Do not use near temperatures above 120°F (50°C). Do not use with cautery or non-explosion proof electrical equipment. Do not use near open flame.

Section 8: EXPOSURE CONTROLS – PERSONAL PROTECTION

Engineering Controls

Use with adequate ventilation.

Respiratory Protection

For clinical setting: minimize inhalation of vapors by patient, especially when applying to head and neck. For large spills (≥ 1000 ppm twa and ≤ 3800 ppm instantaneous exposure): full face, positive pressure, self-contained breathing apparatus should be available for emergency use.

Skin Protection

Wear neoprene or viton gloves for exposures ≥ 1000 ppm TWA and ≤ 3800 ppm instantaneous exposure.

Eye Protection

Splash goggles or safety glasses.

Exposure Limits

OSHA – 1000ppm PELACGLIH – 100 ppm TLV, A3 IDHL – 3800 ppm LEL ACGIH – 100ppm TLV

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	54.1°F (12.3°C)	Specific Gravity (@ 68°F):	0.8939
Freezing Point:	-213.5°F (-136.4°C)	pH:	Essentially neutral
Evaporation Rate (Butyl Acetate = 1):	Greater than 1	Solubility in Water	Slight by slow hydrolysis
Vapor Density (Air = 1 @ 70°F):	2.23	Odor:	Ethereal
Vapor Pressure (@ 68°F):	20.1 psia (5.4 psig)	Appearance:	Clear and colorless liquid or gas
Flash Point:	-58°F (-50°C) TCC; -45°F (-43°C) TOC	Flammable Limits in Air (% by volume):	Lower: 3.8% Upper: 15.4%
Autoignition Temperature:	966°F (519°C)	MOLECULAR WEIGHT	64.52

Section 10: STABILITY AND REACTIVITY

Stability	Normally stable in air. In presence of moisture, slowly hydrolyses forming hydrochloric acid.
Hazardous Decomposition Products	Carbon monoxide, hydrogen chloride gas, phosgene gas, and carbon dioxide.
Incompatible Materials	Alkali metals such as sodium, and potassium, powdered metals such as aluminum, zinc and magnesium and strong oxidizers.
Hazardous Polymerization	Not expected to occur.
Conditions to Avoid	Contact with incompatible materials and exposure to heat, sparks and other sources of ignition and exposure to high heat.

Section 11: TOXICOLOGICAL INFORMATION

Routes of Exposure:	
Acute Inhalation LC50	60,632 ppm (rat) (2 hr.) Anesthetic effects.
Skin Irritation	Produces frostbite.
Eye Irritation	Produces frostbite.
Chronic Effects	Not listed as a carcinogen or suspected carcinogen by NTP or OSHA. Listed under IARC in Group 3: Not classifiable.
Effects of overexposure:	
Acute	Inhalation: Can produce varying degrees of intoxication; i.e. loss of coordination, drunkenness, possible convulsions, abdominal cramps, nausea and coma. It has been reported that concentrated vapors can produce narcotic and anesthetic effects in humans and may produce deep or even fatal anesthesia. Inhalation may also be irritating to the respiratory tract. Eye/Skin: Liquid spilled on skin may cause possible frostbite. For eye contact, there are no specific known effects, but the effects may be the same as contact with skin.
Sub Chronic	Increased liver weights were observed in rats and mice after exposure to 2500, 5000, 10,000 and 19,000 ppm for 6 hours/day, 5 days/week for 13 weeks. No other effects were observed in the study.
Carcinogenicity	Carcinomas of the uterus were observed in female mice exposed to 15,000 ppm during the course of a 2-year inhalation study.

Section 11: TOXICOLOGICAL INFORMATION (Continued)			
Mutagenesis	Has been shown to be mutagenic in bacteria, with and without activation. A 2-year study in mice did not yield increases in bone marrow micronuclei.		
Reproductive/Developmental	No teratogenic effects were observed in mice exposed to 500, 1500 or 5000 ppm during organogenesis. No effects on reproductive organs were observed after 13 weeks exposure to vapors.		
Section 12: ECOLOGICAL INFORMATION			
Environmental Stability	Gas is dissipated rapidly in a ventilated area.		
Effect on Plants and Animals	Suspected to have toxic effects with long term exposure to: central nervous system depression, liver and kidney. No information on adverse effects to plant life except for frost produced upon evaporation.		
Effect on Aquatic Life	No evidence currently available.		
Section 13: DISPOSAL CONSIDERATIONS			
Waste disposal must be in accordance with appropriate Federal, State and local regulations.			
Section 14: TRANSPORT INFORMATION			
Proper Shipping Name	Ethyl Chloride		
Hazard Class	2.1 (Flammable Gas)		
Identification Number	UN 1037		
Packing Group	I (49 CFR 173.322)		
Reportable Quantity	100 LBS./45.4 Kg		
DOT Label(s) Required	Flammable Gas		
Canada TDG Description	Ethyl Chloride, Class 2.1, UN1037 **Special Commodity**		
Section 15: REGULATORY INFORMATION			
USA TSCA:	Listed	Canada DSL:	Listed
Europe EINECS:	Listed	Australia AICS:	Listed
Korea ECL:	Listed	Japan MITI (ENCS):	Listed
SARA Title III	Section 302: Not listed. Sections 311, 312: Acute health hazard. Section 313: Listed.		
CERCLA	Listed with a reportable quantity of 100 lbs.		
State Regulatory Information:	Alaska California Florida Massachusetts Michigan Minnesota Missouri New Jersey New York Pennsylvania Rhode Island Texas West Virginia Wisconsin	Designated Toxic and Hazardous Substances Permissible Exposure Limits for Chemical Contaminants Substance List Substance List Critical Materials Register List of Hazardous Substances Employer Information/Toxic Substance List Right to Know Hazardous Substance List Hazardous Substance List Regulated Substance List Hazardous Substance Hazardous Substance List Hazardous Substance List Toxic and Hazardous Substances	CANADA Regulations (WHMIS): Class A – Compressed Gas Class B1 – Flammable Gas Canadian NPRI – Listed EUROPEAN UNION CLASSIFICATION: Hazard Symbol: F+; Xn Risk Phrases: R12-40-52/53 Safety Phrases: S(2-) 9-16-33-36/37-61
California Proposition 65:	Ethyl Chloride is on the California Proposition 65 lists. This product contains a chemical known to the State of California to cause cancer.		
Section 16: OTHER INFORMATION			
This MSDS was revised and updated as of 04/23/2013 by Gebauer Company.			
INFORMATION CONTAINED IN THIS MATERIAL SAFETY DATA SHEET IS OFFERED WITHOUT CHARGE FOR USE BY TECHNICALLY QUALIFIED PERSONNEL AT THEIR DISCRETION AND RISK. ALL STATEMENTS, TECHNICAL INFORMATION AND RECOMMENDATIONS CONTAINED HEREIN ARE BASED ON TESTS AND DATA WHICH WE BELIEVE TO BE RELIABLE, BUT THE ACCURACY OR COMPLETENESS THEREOF IS NOT GUARANTEED AND NO WARRANTY OF ANY KIND IS MADE WITH RESPECT THERETO. THIS INFORMATION IS NOT INTENDED AS A LICENSE TO OPERATE UNDER OR A RECOMMENDATION TO PRACTICE OR INFRINGE ANY PATENT OF THIS COMPANY OR OTHER COVERING ANY PROCESS, COMPOSITION OF MATTER OR USE. SINCE THE COMPANY SHALL HAVE NO CONTROL OF THE USE OF THE PRODUCT DESCRIBED HEREIN, THE COMPANY ASSUMES NO LIABILITY OF LOSS OR DAMAGE INCURRED FROM THE PROPER OR IMPROPER USE OF SUCH PRODUCT.			

PRODUCT SAFETY DATA SHEET**Product name:** euflexxa® (1% sodium hyaluronate)

SDS Version: Draft 1.0

Revision date: 5/18/2015

Print date: 5/18/2015



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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY**Product name:** euflexxa® (1% sodium hyaluronate)

Finished Form: Liquid

Trade Name: N/A**Synonyms:** N/A**Intended Use:** Finished pharmaceutical product

Ferring Pharmaceuticals Inc.
100 Interpace Parkway
Parsippany, NJ 07054
USA +1 973 796 1600

Emergency telephone number:

ChemTel (24 hours): Domestic: 1-800-255-3924; International: +01-813-248-0585

2. HAZARDS IDENTIFICATION**2.1 Substance or mixture classification****GHS Classification in accordance with 29 CFR 1910.1200(d)**

Not a hazardous substance or mixture

2.2 GHS Label Elements

Not a hazardous substance or mixture

2.3 Hazards not otherwise classified - none**3. COMPOSITION/INFORMATION ON INGREDIENTS****Hazardous Components - none****4. FIRST-AID MEASURES**

Inhalation: As a precaution, move injured person into fresh air and keep person calm under observation.

Skin contact: Remove contaminated clothes and rinse skin thoroughly with water as a precaution.

Eye contact: Do not rub eye. Flush eyes with water as a precaution.

Ingestion: Rinse mouth and drink plenty of water as a precaution.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

Special hazards: During fire, gases hazardous to health may be formed.
 Wear a self-contained breathing apparatus in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Under normal handling conditions an accidental release is highly unlikely.

Personal precautions: For personal protection, see section 8. Follow precautions for safe handling described in this safety data sheet.

Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Methods for cleaning up: Collect spillage with a moist cloth. For waste disposal, see Section 13.

PRODUCT SAFETY DATA SHEET**Product name:** euflexxa® (1% sodium hyaluronate)

SDS Version: Draft 1.0

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7. HANDLING AND STORAGE

Safe handling advice: Observe good laboratory hygiene practices.

If liquid is spilled avoid contact with eyes, skin, and clothing.
 Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
 Wash hands and any exposed skin after removal of PPE, as a precaution.

Technical measures: Work practice should minimize contact. Keep the workplace clean. Do not eat, drink or smoke when using the product. Do not store tobacco, food or beverage in work rooms or areas where the product is used.

Technical measures for safe storage: Store as directed by product packaging.

Storage conditions: Store as directed by product packaging.

Specific end use: None other than those listed in Section 1.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limit values: Contains no substances with Occupational Exposure Limits

During normal handling operations of the liquid

Exposure controls: None needed during normal handling operations.

Respiratory protection: None needed during normal handling operations or spill.

Hand protection: None needed during normal handling operations.
 In the event of a spill, chemical resistant gloves should be worn for clean-up (disposable nitrile gloves).

Eye protection: None needed during normal handling operations.

Skin protection: None needed during normal handling operations.

Hygiene measures: Wash hands after handling. When using do not eat, drink or smoke.
 In the event of contact with the product. Remove contaminated clothing and wash the skin thoroughly with soap and water after work, as a precaution.

Environmental Exposure Controls: None needed during normal handling operations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid
 Odor: No data available
 Odor threshold: No data available
 pH: No data available
 Melting point: No data available
 Boiling point: No data available
 Flash point: No data available
 Evaporation rate: No data available
 Flammability: No data available
 Explosion limits: No data available
 Relative density: No data available

PRODUCT SAFETY DATA SHEET**Product name:** euflexxa® (1% sodium hyaluronate)

SDS Version: Draft 1.0

Revision date: 5/18/2015

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Solubility: Soluble in water

Partition coefficient: No data available
(n-octanol/water)

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Other information: None

10. STABILITY AND REACTIVITY

Reactivity and Chemical Stability: Stable under normal conditions of use.

Conditions/materials to avoid: No data available

Hazardous decomposition products: No data available

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the hazardous components listed in Section 2.

Inhalation: No data available

Skin contact: No data available

Eye contact: No data available

Ingestion: No data available

Specific effects: No information available

Carcinogenicity: No component of this product is present at levels greater than or equal to 0.1% is identified as a probable, possible or confirmed human carcinogen by IARC; or a known or anticipated carcinogen by NTP; or a carcinogen or potential carcinogen by ACGIH or OSHA.

12. ECOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the hazardous components listed in Section 2.

Toxicity: No information available.

Persistence and degradability: No information available.

Bioaccumulative potential: No information available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose of waste and residues in accordance with local authority requirements.

14. TRANSPORT INFORMATION

Transported as a pharmaceutical finished product.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

PRODUCT SAFETY DATA SHEET**Product name:** euflexxa® (1% sodium hyaluronate)

SDS Version: Draft 1.0

Revision date: 5/18/2015

Print date: 5/18/2015



Page 4 of 4

15. REGULATORY INFORMATION

NONE

16. OTHER INFORMATION**Date of SDS Preparation: 05/18/15****Current Version Preparation: 5/18/15**

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions. The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

SAFETY DATA SHEET



EXPRESS GEL HAND SANITIZER

Section 1. Chemical product and company identification

Product name : EXPRESS GEL HAND SANITIZER
Recommended use and restrictions : Skin Cleaner
 Use only for the purpose on the product label.

Product dilution information : Not applicable

Supplier's information : Ecolab Inc. Healthcare Division
 370 N. Wabasha St.
 St. Paul, MN 55102
 1-866-781-8787
Code : 915392
Date of issue : 09 Oct 2013
 EMERGENCY HEALTH INFORMATION: 1-800-328-0026
 Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Hazards identification

GHS Classification : **Product AS SOLD**
 : FLAMMABLE LIQUIDS - Category 3
 : SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2B

GHS label elements

Signal word : Warning
Symbol :



Hazard statements : Flammable liquid and vapor.
 : Causes eye irritation.

Precautionary statements

Prevention : Keep away from heat, sparks, open flames and hot surfaces. - No smoking. Keep container tightly closed. No special protection is required.
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 attention.
Storage : Store in a well-ventilated place. Keep cool.
Disposal : See section 13 for waste disposal information.
Other hazards : None known.

Product AT USE DILUTION
 Product is sold ready to use.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Product AS SOLD

Hazardous ingredients	Concentration Range (%)	CAS number
ALCOHOL	>50	64-17-5

Product AT USE DILUTION

Hazardous ingredients	Concentration Range (%)	CAS number
Product is sold ready to use.		

Section 4. First aid measures

	Product AS SOLD	Product AT USE DILUTION
Eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse with water for a few minutes.	Product is sold ready to use.
Skin contact	: Get medical attention if symptoms appear.	
Inhalation	: No special measures required. Treat symptomatically.	
Ingestion	: Get medical attention if symptoms occur.	
Protection of first-aiders	: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.	
Notes to physician	: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.	

See toxicological information (section 11)

Section 5. Fire-fighting measures

Product AS SOLD

Suitable fire extinguishing media	: Use water spray, fog or foam.
Specific hazards arising from the chemical	: Flammable liquid and vapor. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Runoff to sewer may create fire or explosion hazard.
Hazardous thermal decomposition products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide
Specific fire-fighting methods	: 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.
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

	Product AS SOLD
Personal precautions	: Eliminate all ignition sources. No special measures required.
Environmental precautions	: Avoid contact of large amounts of spilled material and runoff with soil and surface waterways.
Methods for cleaning up	: Absorb with an inert material. Use a water rinse for final clean-up.

Product AT USE DILUTION

Product is sold ready to use.

Section 7. Handling and storage

	Product AS SOLD
Handling	: Keep away from heat, sparks and flame. To avoid fire, eliminate ignition sources. Wash hands after handling.
Storage	: Keep out of reach of children. Keep container tightly closed. Keep container tightly closed and sealed until ready for use. Keep container in a cool, well-ventilated area. Avoid all possible sources of ignition (spark or flame). Store in a segregated and approved area. Do not store above the following temperature: 50°C

Product AT USE DILUTION

Product is sold ready to use.

Section 8. Exposure controls/personal protection

Control parameters

Ingredient name	Exposure limits
ALCOHOL	ACGIH TLV (United States, 3/2012). STEL: 1000 ppm 15 minutes. OSHA PEL (United States, 6/2010). TWA: 1900 mg/m ³ 8 hours. TWA: 1000 ppm 8 hours. NIOSH REL (United States, 6/2009). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours.

	Product AS SOLD
Appropriate engineering controls	: No special ventilation requirements.
Personal protection	
Eye protection	: No special protection is required.
Hand protection	: No special protection is required.
Skin protection	: No special protection is required.
Respiratory protection	: No special protection is required.
Hygiene measures	: No special measures required.

Product AT USE DILUTION

Product is sold ready to use.

Section 9. Physical and chemical properties

	Product AS SOLD
Physical state	: Gel
Color	: Colorless
Odor	: Fragrance-like
pH	: 6.5 to 7.5 (100%)
Flash point	: 24 °C (Closed cup)
Explosion limits	: Not available.
Flammability (solid, gas)	: Not available.
Melting point	: Not available.
Boiling point	: >35°C (>95°F)
Evaporation rate (butyl acetate = 1)	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: 0.852 to 0.858 (Water = 1)
Solubility	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Odor threshold	: Not available.
Viscosity	: Dynamic (room temperature): 6000 mPa·s (6000 cP)

Product AT USE DILUTION

Product is sold ready to use.

Section 10. Stability and reactivity

Product AS SOLD

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.
Materials to avoid	: Not available.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Route of exposure : Skin contact, Eye contact, Inhalation, Ingestion

Product AS SOLD

Symptoms

Eye contact	: Adverse symptoms may include the following: irritation watering redness
Skin contact	: No specific data.
Inhalation	: No specific data.
Ingestion	: No specific data.

Acute toxicity

Product AT USE DILUTION

Product is sold ready to use.

Section 11. Toxicological information

Eye contact : Causes eye irritation.
Skin contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Toxicity data

Product/ingredient name

ethanol	LC50 Inhalation	Rat	117 mg/l
	Vapor		
	LD50 Dermal	Rabbit	15800 mg/kg
	LD50 Oral	Rat	10470 mg/kg

Chronic toxicity

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.

Section 12. Ecological information

Product AS SOLD

Ecotoxicity : No known significant effects or critical hazards.

Aquatic and terrestrial toxicity

Product/ingredient name	Result	Species	Exposure
ethanol	Acute LC50 11000 mg/l	Fish	96 hours

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : **Product AS SOLD**
 : Avoid disposal. Attempt to use product completely in accordance with intended use. Disposal should be in accordance with applicable regional, national and local laws and regulations.
RCRA classification : Unused product is D001 (Ignitable)

Product AT USE DILUTION
 Product is sold ready to use.

Section 14. Transport information

Certain shipping modes or package sizes may have exceptions from the transport regulations. The classification provided may not reflect those exceptions and may not apply to all shipping modes or package sizes.

DOT

DOT Classification : UN1170
DOT Proper shipping name : Ethanol solutions
Class : 3
Packing group : III

IMO/IMDG

IMO/IMDG Classification : UN1170
IMO/IMDG Proper shipping name : ETHANOL SOLUTION
Class : 3
Packing group : III

Section 14. Transport information

For transport in bulk, see shipping documents for specific transportation information.

Product AT USE DILUTION

Not intended for transport.

Section 15. Regulatory information

Product AS SOLD

U.S. Federal regulations

TSCA 8(b) inventory : At least one component is not listed.

SARA 302/304/311/312 extremely hazardous substances: No listed substance

SARA 302/304 emergency planning and notification: No listed substance

SARA 313

Product name

CAS number

Concentration

Form R - Reporting requirements : No listed substance

California Prop. 65 : No listed substance

Section 16. Other information

Product AS SOLD

Hazardous Material :
Information System (U.S.A.)

Health	*	1
Flammability		3
Physical hazards		0

National Fire Protection Association (U.S.A.) :



Date of issue : 09 Oct 2013

Prepared by : Regulatory Affairs
1-800-352-5326

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

SAFETY DATA SHEET

**GOJO® Clear & Mild Foam Handwash**

Version 1.0

SDS Number: 400000000152

Revision Date: 09/20/2016

SECTION 1. IDENTIFICATION

Product name : GOJO® Clear & Mild Foam Handwash

Manufacturer or supplier's details

Company name of supplier : GOJO Industries, Inc.

Address : One GOJO Plaza, Suite 500
Akron, Ohio 44311

Telephone : 1 (330) 255-6000

Emergency telephone number : 1-800-424-9300 CHEMTREC

Recommended use of the chemical and restrictions on use

Recommended use : Skin-care

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**

Eye irritation : Category 2B

GHS label elements

Signal word : Warning

Hazard statements : H320 Causes eye irritation.

Precautionary statements : **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.

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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**Hazardous components**

Chemical name	CAS-No.	Concentration (%)
Sodium Laureth Sulfate	68585-34-2	>= 1 - < 5
Glycerin	56-81-5	>= 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. If symptoms persist, call a physician.
In case of skin contact	: Wash with water and soap as a precaution. Get medical attention if irritation develops and persists.
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. Seek medical advice.
If swallowed	: If swallowed, DO NOT induce vomiting. Rinse mouth with water. Obtain medical attention.
Most important symptoms and effects, both acute and delayed	: Causes eye irritation.
Protection of first-aiders	: First Aid responders should pay attention to self-protection and use the recommended protective clothing

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	: None known.
Hazardous combustion products	: Sulphur oxides Carbon oxides Nitrogen oxides (NOx) Metal oxides

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- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use a water spray to cool fully closed containers.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Ensure adequate ventilation.
Evacuate personnel to safe areas.
Material can create slippery conditions.
- 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 : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Keep in suitable, closed containers for disposal.
Clean contaminated floors and objects thoroughly while observing environmental regulations.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : For personal protection see section 8.
Do not swallow.
Avoid contact with eyes.
Keep container closed when not in use.
- Conditions for safe storage : Keep in properly labelled containers.
Keep container tightly closed in a dry and well-ventilated place.
Store in accordance with the particular national regulations.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis

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		exposure)	concentration	
Glycerin	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1

Personal protective equipment

Respiratory protection	: No personal respiratory protective equipment normally required.
Eye protection	: No special measures necessary provided product is used correctly. Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	: No special measures necessary provided product is used correctly.
Protective measures	: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. Ensure that eye flushing systems and safety showers are located close to the working place.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: clear, colourless, light yellow
Odour	: like soap
Odour Threshold	: No data available
pH	: 5.3 - 6.7, (20 °C)
Solidification / Setting point	: 1.4 °C
Initial boiling point and boiling range	: 98 °C
Flash point	: > 100 °C
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit	: No data available

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Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Density	: 1.012 g/cm ³
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: not determined
Thermal decomposition	: The substance or mixture is not classified self-reactive.
Viscosity	
Viscosity, kinematic	: 10 - 20 mm ² /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	: No dangerous reaction known under conditions of normal use.
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Skin contact

Eye contact

Inhalation

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method

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Components:**Sodium Laureth Sulfate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
 Assessment: The substance or mixture has no acute oral toxicity

Glycerin:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Assessment: Not irritating when applied to human skin.

Result: No skin irritation

Components:**Sodium Laureth Sulfate:**

Result: Skin irritation

Glycerin:

Result: No skin irritation

Serious eye damage/eye irritation

Causes eye irritation.

Product:

Result: Mild eye irritation

Components:**Sodium Laureth Sulfate:**

Result: Eye irritation

Remarks: Severe eye irritation

Glycerin:

Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:**Glycerin:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
 Method: OECD Test Guideline 476
 Result: negative

Carcinogenicity

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Not classified based on available information.

Components:**Glycerin:**

Species: Rat

Application Route: Ingestion

Exposure time: 2 Years

Result: negative

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component 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 component 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.

Components:**Glycerin:**

Effects on fertility

: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative**STOT - single exposure**

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Sodium Laureth Sulfate:**Repeated dose toxicity -
Assessment

: Causes serious eye irritation.

Glycerin:

Species: Rat

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NOAEL: 167 mg/m³
 LOAEL: 660 mg/m³
 Application Route: inhalation (dust/mist/fume)
 Exposure time: 13 w
 Symptoms: Local irritation

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Glycerin:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,955 mg/l
 aquatic invertebrates Exposure time: 48 h

Toxicity to bacteria : NOEC (Pseudomonas putida): > 10,000 mg/l
 Exposure time: 16 h

Persistence and degradability**Components:****Sodium Laureth Sulfate:**

Biodegradability : Result: Readily biodegradable.

Glycerin:

Biodegradability : Result: Readily biodegradable.
 Biodegradation: 94 %
 Exposure time: 1 d

Bioaccumulative potential**Components:****Glycerin:**

Partition coefficient: n- : log Pow: -1.76
 octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of
 Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

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Class I or Class II ODS as defined by the U.S. Clean Air Act
Section 602 (40 CFR 82, Subpt. A, App.A + B).

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.

SECTION 14. TRANSPORT INFORMATION**International Regulation****IATA-DGR**

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act****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 : Acute Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Glycerin	56-81-5	1.75 %

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This product does not contain any VOC exemptions listed under the U.S. Clean Air Act Section 450.

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

Glycerin	56-81-5	1 - 5 %

Pennsylvania Right To Know

Water (Aqua)	7732-18-5	90 - 100 %
Glycerin	56-81-5	1 - 5 %

New Jersey Right To Know

Water (Aqua)	7732-18-5	90 - 100 %
Sodium Laureth Sulfate	68585-34-2	1 - 5 %
Glycerin	56-81-5	1 - 5 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:

CH INV	: On the inventory, or in compliance with the inventory
TSCA	: On the inventory, or in compliance with the inventory
DSL	: All components of this product are on the Canadian DSL.
AICS	: On the inventory, or in compliance with the inventory
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: On the inventory, or in compliance with the inventory
ISHL	: On the inventory, or in compliance with the inventory
KECI	: On the inventory, or in compliance with the inventory
PICCS	: On the inventory, or in compliance with the inventory
IECSC	: On the inventory, or in compliance with the inventory

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

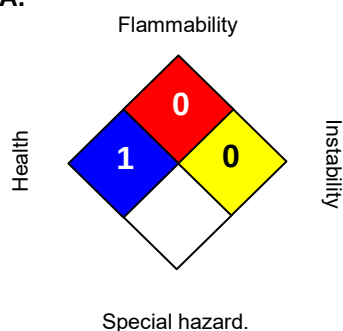
SAFETY DATA SHEET

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SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

Revision Date : 09/20/2016

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.

Product Name: Humira (R) (Adalimumab) Citrate Free
Issued: Mar-17-2017



SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Humira (R) (Adalimumab) Citrate Free

List Number: 0554; 0243

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

Recommended use: Pharmaceuticals

1.3. Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
 1 North Waukegan Road
 North Chicago, IL 60064
 USA
 +1-847-932-7900

E-mail Address: AbbVie.SDS@abbvie.com

1.4. Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
 or +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

2.2. Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No

Product Name: Humira (R) (Adalimumab) Citrate Free
Issued: Mar-17-2017

Water 7732-18-5	80-90	Present		Not Hazardous*	No data available
Adalimumab L-02-3126	5-10	NA		Not Hazardous*	No data available
Mannitol 69-65-8	1-5	Present		Not Hazardous*	No data available
Polysorbate 80 9005-65-6	<1	NA		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

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: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms No signs and symptoms from occupational exposure are known. Clinical data suggests the following: headaches, coughing, rash, dizziness, nasal discharge, fever, gastrointestinal upset, leucopenia, variable cardiovascular system effects.

Medical Conditions Aggravated by Exposure None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: gastrointestinal system, cardiovascular system, lymphatic system, or hematopoietic system.

4.3. Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

Product Name: Humira (R) (Adalimumab) Citrate Free
Issued: Mar-17-2017

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3. Advice for firefighters

Protective Equipment and Precautions 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

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Disinfect with 10% (v/V) bleach solution. Dispose of material as directed in Section 13.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Water 7732-18-5	Not applicable	None
Adalimumab L-02-3126	200 mcg/m ³	None
Mannitol 69-65-8	Not applicable	None
Polysorbate 80 9005-65-6	Not applicable	None

Product Name: Humira (R) (Adalimumab) Citrate Free
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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal conditions. When handling bulk formulation, use in a well-ventilated area.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Clear/Colorless Solution

Odor: Odorless.

Odor Threshold: Not determined

pH: 4.7-5.7

Boiling Pt. @ 760 mm Hg (°C): Not determined

Melting/Freezing Point (°C): Not determined

Flash Point (°C): Not determined

Evaporation Rate at 20°C: Not determined

Flammability (Solid): Not determined

Lower Explosive Limit: Not determined

Upper Explosive Limit: Not determined

Vapor Pressure (mm Hg): Not determined

Vapor Density (Air = 1): Not determined

Density, g / mL: 1.01-1.05

Specific Gravity: Not determined

Solubility(ies): Freely soluble in: water.

Partition coefficient: Not determined

n-octanol/water

Autoignition Temp. (°C): Not determined

Decomposition temperature (°C): Not determined

Viscosity (centipoise): Not determined

Explosion Severity: Not determined

Oxidizer Properties: Not determined

9.2. Other information

Not determined

Product Name: Humira (R) (Adalimumab) Citrate Free
Issued: Mar-17-2017

SECTION 10: Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Mannitol 69-65-8	LD50 =	13,500-22,000	mg/kg	Mice Rats
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

Acute Toxicity - Dermal: Not determined

Acute Toxicity - Inhalation: Not determined

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Adalimumab L-02-3126	ALD (iv) >	898	mg/kg	Rats Mice	None

Corrosivity: Not determined

Dermal Irritation: Active Ingredient(s): Produced little or no skin irritation in animals.

Eye irritation: Not determined

Product Name: Humira (R) (Adalimumab) Citrate Free
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Sensitization: Not determined

Toxicokinetics/Metabolism: Not determined

Target Organ Effects Data for component (s) given below:

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Adalimumab L-02-3126	Hematopoietic system Lymphatic system	Mice Liquid Monkeys	> 82.9	mg/kg/wk	Intravenous	Variable exposure periods
Mannitol 69-65-8	Eyes Kidney	Rats Mice	25,000	ppm	Oral Diet	Repeat dose study (ies).

Reproductive Effects Active Ingredient : Animal testing did not show any effects on fetal development
 Animal testing did not show any effects on fertility

Chemical Name	Species	Dosage	Units	Route	Duration
Adalimumab L-02-3126	Monkeys	< 100	mg/kg/wk	Intravenous	Variable Treatment Regimens

Carcinogenicity Not determined

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Adalimumab L-02-3126	Negative	Negative	No Data.	No Data.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

SECTION 12: Ecological information

12.1. Toxicity

Not determined

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Product Name: Humira (R) (Adalimumab) Citrate Free
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Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

SECTION 14: Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN number: Not applicable
 14.2. Proper shipping name: Not applicable
 14.3. Hazard class: Not applicable
 14.4. Packing group: Not applicable
 14.5. Environmental hazard: Not applicable
 14.6. Special provisions: Not applicable
 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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Water 7732-18-5	Present	X	X	Not listed	X
Adalimumab L-02-3126	-	-	-	Not listed	-
Mannitol 69-65-8	Present	X	X	Not listed	X
Polysorbate 80 9005-65-6	-	X	X	Not listed	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Water 7732-18-5	-	-	X	X	Present	
Adalimumab L-02-3126	-	-	-	-	-	
Mannitol 69-65-8	Present	Present	X	X	Present	
Polysorbate 80 9005-65-6	Present	Present	X	X	Present	

Product Name: Humira (R) (Adalimumab) Citrate Free
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Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
 TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
 DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
 PICCS - Philippines Inventory of Chemicals and Chemical Substances
 ENCS - Japan Existing and New Chemical Substances
 ISHL - Japan Industrial Safety and Health Law
 IECSC - China Inventory of Existing Chemical Substances
 AICS - Australian Inventory of Chemical Substances
 KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Water	80-90	Not listed	Not listed	Not listed
Adalimumab	5-10	Not listed	Not listed	Not listed
Mannitol	1-5	Not listed	Not listed	Not listed
Polysorbate 80	<1	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	80-90	No	Not applicable	Not applicable
Adalimumab	5-10	No	Not applicable	Not applicable
Mannitol	1-5	No	Not applicable	Not applicable
Polysorbate 80	<1	No	Not applicable	Not applicable

RCRA Status: Not determined

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class Exempt

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

SECTION 16: Other information

Document Authored By: Occupational and Environmental Toxicology

Issued: Mar-17-2017

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Safety Data Sheet

Hyalgan (sodium hyaluronate)



Safety Data Sheet dated 27/4/2015, version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

This Safety Data Sheet has been updated in accordance with the Global Harmonized System and 29 CFR 1910.1200 Appendix D

1.1. Product identifier

Trade name: Hyalgan® (sodium hyaluronate)

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

Product type and use Intra-articular Injection

1.3. Details of the manufacturer of the safety data sheet

Company Fidia Farmaceutici spa
Address Via Ponte della Fabbrica, 3/A
District and Country 35031 - Abano Terme (PD)
Italy
tel. +39 49 8232111
fax +39 49 8232299

e-mail address SDSinfo@fidiapharma.it

1.4. Emergency telephone number

References to emergency information **Fidia Farmaceutici spa tel. +39 49 8232111**
available Monday to Friday (except holidays) from 8:30 a.m. to 5:30 p.m. (local time)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

Classification according to Regulation (EC) n. 1272/2008 [EU-GHS/CLP]

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Classification according to paragraph (d) of 29 CFR 1910.1200

Not a hazardous substance or mixture according to regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2. Label elements.

Labelling according to Regulation (EC) n. 1272/2008 [EU-GHS/CLP] or 29 CFR 1910.1200

Labelling not applicable. Not a hazardous substance or mixture according to both regulations .

Labelling according to Directive 67/548/EEC

Labelling not applicable.

2.3. Other hazards

Based on the available data of this product no hazardous properties are known.

Safety Data Sheet

Hyalgan (sodium hyaluronate)



3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Composition

Chemical Name	Concentration	CAS No.	EC No.
Hyaluronic acid sodium salt (Hyalectin®)	1%	9067-32-7	-
Sodium chloride	0.8%	7647-14-5	231-598-3
Sodium phosphate dibasic dodecahydrate	0.06%	10039-32-4	231-448-7
Sodium dihydrogen phosphate dihydrate	0.01%	13472-35-0	231-449-2
Water for Injections BP	As needed	7732-18-5	231-791-2

3.2 Mixtures

Not a hazardous substance or mixture according to EC-directives 67/548/EEC, 1999/45/EC, Regulation (EC) No. 1272/2008 or 29 CFR 1910.1200.

4. FIRST AID MEASURES

4.1. Description of first aid measures

Eye contact	Rinse cautiously with plenty of water for 15 minutes also raising the eyelids. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation, blurred vision or swelling occurs and persists, consult your doctor.
Inhalation	In case of symptoms arising from inhalation of product fumes, mists or vapor: Remove patient to a quiet and well ventilated place if safe to do so. Seek medical assistance if breathing remains difficult.
Skin contact	Wash the area with soap and water. Seek medical attention if skin irritation develops and persists.
Ingestion	Thoroughly rinse the mouth out with water (only if the injured person is conscious). In case of a reaction, seek medical assistance

4.2. Most important symptoms and effects, both acute and delayed

No adverse effects are expected.

4.3. Indication of immediate medical attention and special treatment needed

No data available

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Recommended

extinguishers:

Water, Foam, CO₂, Dry chemical powders, according to the materials involved in the fire.

Extinguishers not to be used:

None known.

5.2. Special hazards arising from the substance or mixture

Avoid inhaling the fumes in case of fire.

5.3. Advice for firefighter protective equipment:

Use protection for the respiratory tract.

Wear respirator, gloves, protective footwear.

CAUTION: it's recommended the use of breathing apparatus and full protection for firefighting, since the combustion may generate toxic fumes. If possible contain water used for firefighting and collect for later disposal.

Safety Data Sheet

Hyalgan (sodium hyaluronate)



6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Handle in accordance with good industrial hygiene and safety practice.

6.2. Environmental measures

No adverse effects are expected.

6.3. Methods and materials for containment and cleaning up

Immediate actions:

- Stop the liquid product from leaking, if possible and if this does not present a risk for people.
- Create a barrier to prevent the liquid product from reaching streams and sewers.

Cleaning actions:

- Gather up any pieces of glass with a broom and the liquid state with absorbent material while being careful to not cut yourself.
- Collect what has been spilled in a container, and then send it to waste disposal.
- Air out and thoroughly wash the area affected with water.

Special precautions:

Dress in a proper manner in order to reduce the chance of contact with skin and eyes to a minimum.
Use gloves to prevent being cut by slivers of glass that could result from breakage of the syringes.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. For personal protection, see section 8.

Recommended equipment and procedures: Observe precautions stated on label.

Prohibited equipment and procedures:

No smoking, eating or drinking in areas where the product is used.

Wear suitable protective clothing and gloves

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry, ventilated place

Keep away from the light

Store at temperatures lower than 25°C, but not at freezing temperatures: even though nothing changes from the safety viewpoint, the product could degrade and lose its pharmacological characteristics

Do not store the product for periods longer than 36 months: even though nothing changes from the safety viewpoint, it could degrade and lose the pharmacological characteristics associated with it

Packaging: Always keep in original packaging.

Incompatible materials: None known

7.3. Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure controls

Respiratory protection:

Handle in accordance with good industrial hygiene and safety practice.

Safety Data Sheet

Hyalgan (sodium hyaluronate)



Make sure there is adequate ventilation where product is used or stored

Protection for hands:

Cut-resistance gloves should be worn.
Wash hands after handling.

Eye protection: None in particular.

Protection for skin: None in particular.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Clear liquid
Color	Colorless
Odor	odorless
Odor threshold	Not applicable
pH	6.8 -7.5 [20°C]
Melting point/freezing point	Not determined
Boiling point & range	Not determined
Flashpoint	Not determined
Evaporation rate	Not determined
Flammability	Not determined
Explosive limits	No explosive properties
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	It is an aqueous solution
Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Viscosity	1.0-1.5 m ³ /kg

9.2 Other information

No additional information.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2. Chemical stability

This product is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

Do not freeze the product

The product is sensitive to sunlight

Do not storage at temperatures higher the 77°F (25°C)

10.5. Incompatible materials

Avoid strong oxidizing agents

Do not use with quaternary ammonium salts. It may cause precipitation of HA.

10.6. Hazardous decomposition products

Carbon monoxide, carbon dioxide and nitrous oxides could be generated by decomposition of the liquid state

Safety Data Sheet

Hyalgan (sodium hyaluronate)



11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

No known significant effects or critical hazards. Handle in accordance with good industrial hygiene and safety practice.
Sodium hyaluronate is a non-hazardous polysaccharide present in the extra cellular matrix of all tissues in all vertebrates.

11.2. Acute toxicity exposure

Based on available data, the classification criteria are not met.

11.3. Chronic exposure

The following information refers to the active ingredient of the liquid state

- Carcinogenic properties: Based on studies carried out up to today, one may deduce that the product has no carcinogenic properties.
- Teratogenic properties: Based on studies carried out up to today, the product has no teratogenic properties.
- Mutagenic properties: Based on studies carried out up to today, the product has no mutagenic properties.
- Risks for the Reproduction System: Based on studies carried out up to today, one may deduce that the product has no properties that present risks for the reproduction system.
-

12. ECOLOGICAL INFORMATION

12.1. Toxicity

No further relevant information available. Given the nature of the liquid product, problems attributable to its hypothetical ecotoxicological properties are not foreseen if used correctly.

12.2. Persistence and degradability

No further relevant information available. Given the nature of the liquid product, negative impacts on the environment are not foreseen if used correctly.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

12.5. Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATION

13.1. Waste treatment methods

The liquid product is not classified as dangerous. It should however be kept in mind that it is a product of biological origin, so it is subject to organic deterioration phenomena up to decomposition.

Pursuant to the laws in force, it is necessary to precisely classify the single waste by chemical analysis, as is true for all other types of substances and products.

Remarks on disposal:

The waste disposal of this product must be carried out in accordance with local laws in force

It is recommended to incinerate the product after having contacted the authorities in charge or specialized and authorized companies that can provide information about how to destroy this waste.

14. TRANSPORT INFORMATION

14.1. The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

Safety Data Sheet

Hyalgan (sodium hyaluronate)



15. REGULATORY INFORMATION

15.1. There are no additional safety, health or environmental regulations specific to this product.

16. OTHER INFORMATION

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)
ICAO:	International Civil Aviation Organization
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
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals LC50: Lethal concentration, 50 percent

Main bibliographic sources:

1. Internal Report - Fidia Research Laboratories Report No 629150 (1983b)
2. The Merck Index. Ed. 10
3. Handling Chemical Safety
4. Registry of Toxic Effects of Chemical Substances
5. INRS - Fiche Toxicologique
6. Patty - Industrial Hygiene and Toxicology
7. N.I. Sax - Dangerous properties of Industrial Materials-7 Ed., 1989
8. 29 CF 1910.1200 (g) and Appendix D, Occupational Safety and Health Standards, Hazard communication, Safety Data Sheet
9. Directive 1999/45/EC and following amendments
10. Directive 67/548/EEC and following amendments and adjustments
11. Regulation (EC) 1907/2006 (REACH) of the European Parliament
12. Regulation (EC) 1272/2008 (CLP) of the European Parliament
13. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
14. Regulation (EC) 453/2010 of the European Parliament

DISCLAIMER OF LIABILITY

The information contained in this document are based on knowledge available at the time of completion, the requirements relating to proper use of the product.

This only refers to the product indicated and constitutes no guarantee, express or implied, regarding its correctness or accuracy.

The user must verify the suitability and completeness of such information in relation to the specific use intended. In case of any uncertainty, please consult the supplier.

The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

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This sheet is the first editions.

Safety Data Sheet HYMOVIS



Safety Data Sheet dated 25/8/2015, version 3

This safety data sheet has been updated in accordance both with the Regulation (EC) n. 1272/2008 (CLP) and with the chapter 1.5 of Global Harmonized System (GHS)

This data sheet is intended only for professional users who handle the active substance or mixture, in large quantities. For the finished product, a package insert with relevant information for the final users is included in the packaged product.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name: HYMOVIS®

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

Product type and use pre-filled syringe (24mg/3ml) for intra-articular Injection

1.3. Details of the supplier of the safety data sheet

Company Fidia Farmaceutici spa
Address Via Ponte della Fabbrica, 3/A
District and Country 35031 - Abano Terme (PD)
Italy
tel. +39 49 8232111
fax +39 49 8232299

e-mail address SDSinfo@fidiapharma.it

1.4. Emergency telephone number

References to emergency information Fidia Farmaceutici spa tel. +39 49 8232111
available from Monday to Friday (except holidays)
from 8:30 a.m. to 5:30 p.m. (local time)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

Classification according to Regulation (EC) n. 1272/2008 [EU-GHS/CLP]

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements.

Labelling according to Regulation (EC) n. 1272/2008 [EU-GHS/CLP]

No labelling applicable. Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3. Other hazards

Based on the available data of this product no hazardous properties are known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Main component:

HYADD®4	N. CAS not available N. CE not available	Not hazardous	Concentration 0.8%

Safety Data Sheet

HYMOVIS



4. FIRST AID MEASURES

Eye contact	Rinse cautiously with plenty of water also raising the eyelids. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation, blurred vision or swelling occurs and persists, consult your doctor.
Inhalation	In case of symptoms arising from inhalation of product fumes, mists or vapor: Remove patient to a quiet and well ventilated place if safe to do so. Seek medical assistance if breathing remains difficult.
Skin contact	Wash the area with soap and water. Seek medical attention if skin irritation develops and persists.
Ingestion	Thoroughly rinse the mouth out with water (only if the injured person is conscious). In case of a reaction, seek medical assistance

4.1. Most important symptoms and effects, both acute and delayed

No adverse effects are expected.

4.2. Indication of immediate medical attention and special treatment needed

No data available

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Recommended extinguishers:

Water, Foam, CO₂, Dry chemical powders, according to the materials involved in the fire.

Extinguishers not to be used:

None known.

5.2. Special hazards arising from the substance or mixture

Avoid inhaling the fumes in case of fire.

5.3. Advice for firefighter protective equipment:

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).

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Handle in accordance with good industrial hygiene and safety practice.

6.2. Environmental measures

No adverse effects are expected.

6.3. Methods and materials for containment and cleaning up

Recover the product for elimination.

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Cleaning actions:

- Gather up any pieces of glass with a broom and the liquid state with absorbent material while being careful to not cut yourself.
- Collect what has been spilled in a container, and then send it to waste disposal.
- Air out and thoroughly wash the area affected with water.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 13 for additional waste treatment information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry, ventilated place.

The product should be stored below 25°C. Do not freeze.

Packaging: Always keep in original packaging.

Incompatible materials: None known.

7.3. Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

No occupational exposure limits were found.

8.2. Exposure controls

Handle in accordance with good industrial hygiene and safety practice.

RESPIRATORY PROTECTION: None in particular. Make sure there is adequate ventilation where product is used or stored.

SKIN PROTECTION: None in particular.

EYE PROTECTION: None in particular.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Clear viscous liquid
Color	Colorless
Odor	Odorless
Odor threshold	Not applicable
pH	6.8 -7.5
Melting point/freezing point	Not determined
Boiling point & range	Not determined
Flashpoint	Not determined
Evaporation rate	Not determined
Flammability	Not determined
Explosive limits	No explosive properties
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	It is an aqueous solution
Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Not determined

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Decomposition temperature
Dynamic Viscosity

Not determined
20-80 Pa_s

9.2 Other information

No additional information.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability

This product is stable under the recommended handling and storage conditions in section 7.

10.3 Possibility of hazardous reactions

The product is stable under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid

Do not freeze the product.

The product should be stored below 25°C.

10.5 Incompatible materials

Avoid strong oxidizing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide and nitrous oxides could be generated by decomposition of the liquid state.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

No known significant effects or critical hazards. Handle in accordance with good industrial hygiene and safety practice.

- There was no evidence of subchronic toxicity after biweekly intraperitoneal injection during a 13-week period of the HYADD4 gel, at 5 mg/ml in the rat;
- There was no mortality or evidence of systemic toxicity from the test article injected into mice (test article HYADD4 8 ml/ml);
- Genotoxicity, in vitro chromosomal aberration study in mammalian cells (extract): under the conditions of assay, the test article extract was not considered genotoxic to Chinese Hamster Ovary cells in the presence or absence of S9 metabolic activation (test article HYADD4 8 ml/ml);
- Cytotoxicity study on HYADD4 (8 mg/ml): under the conditions of assay, there was no evidence of cell lysis or toxicity.

RIF. for all four studies: Fidia Farmaceutici spa internal reports.

Additionally, Sodium hyaluronate is a non-hazardous polysaccharide present in the extra cellular matrix of all tissues in all vertebrates.

a) Acute toxicity;

ORAL - LD₅₀ > 2000 mg/kg bw (species: rat).

The LD50 value found in the literature, compared with the parameters defined in the CLP Regulation (Annex I), do not allow to classify this hazard class.

The bibliography indicates that products containing high percentage of sodium hyaluronate or other glycosaminoglycans and partially hydrolysed proteins were tested without deaths recorded in animals of both sexes in the condition test.

RIF. (FDA 3 (PMA P010029; December 3, 2004); EFSA Journal 2013;11(6):3260; Regulatory Toxicology and Pharmacology 62 (2012) 532–541

CHEMID - Substance Name: Hyaluronate Sodium; [USAN:JAN] RN: 9067327; UNII: YSE9PPT4TH)

based on available data, the classification criteria are not met

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b) Skin corrosion/irritation;

The use of sodium hyaluronate in cosmetic products is considered safe; moreover, its corresponding acid did not cause irritation in rabbits and guinea pigs skin irritation studies. Extensive use of sodium hyaluronate in cosmetic and as dermatological agent allow to exclude this danger.

RIF. (International Journal of Toxicology Volume 28 Number 4S July/August 2009 5-67; DRUGDEX - Hyaluronic acid)

based on available data, the classification criteria are not met

c) Serious eye damage/eye irritation;

Highly purified sodium hyaluronate is used as surgical instrument into eye without any adverse effects and no significant inflammation. Moreover, solution of sodium hyaluronate applied in the eyes of treated animals did not determine a positive response.

RIF. (FDA 3 (PMA P010029; December 3, 2004); International Journal of Toxicology Volume 28 Number 4S July/August 2009 5-67)

based on available data, the classification criteria are not met

d) Respiratory or skin sensitization;

SKIN SENSITIZATION

A skin sensitization study did not show sensitization in guinea pigs.

On the other hand, due to large cosmetic and surgical use, sensitization or allergic episode are not expected

RIF. (FDA 1 (PMA P030019; February 4, 2004); International Journal of Toxicology Volume 28 Number 4S July/August 2009 5-67)

based on available data, the classification criteria are not met

e) Germ cell mutagenicity;

Mutagenicity studies both in-vitro (Ames test, chromosome aberration study in Chinese hamster ovary cells, sister chromatid exchanges study) and in-vivo (bone marrow micronucleus study) have shown that sodium hyaluronate is not genotoxic.

According to this data the substance is not classified for this hazard class.

RIF. (CCRIS SODIUM HYALURONATE CASRN: 9067327; Hyalgan 20 mg/2 ml solution for injection – intraarticular use

Module 2 - CTD Summaries – 2.4 Non Clinical Overview; FDA 1 (PMA P030019; February 4, 2004); FDA 3 (PMA P010029; December 3, 2004))

based on available data, the classification criteria are not met

g) Reproductive toxicity;

Animal studies have shown that sodium hyaluronate did not modify fertility when given at doses approximately 11 times the maximum recommended human dose per treatment cycle.

Furthermore, subcutaneous administration of sodium hyaluronate from day 17 of pregnancy up to 20 days after delivery did not cause skeletal malformations in offspring. Sodium hyaluronate seems to have an important role in oocyte maturation: promotes sperm function including motility, capacitation and the acrosome reaction.

RIF. (Reprotox - Sodium hyaluronate; Shepard 2 - Sodium hyaluronate; Veterinarni Medicina, 53, 2008 (8): 397–411; Hyalgan 20 mg/2 ml solution for injection – intra-articular use Module 2 - CTD Summaries – 2.4 Non Clinical Overview)

based on available data, the classification criteria are not met

h) Specific target organ toxicity - single exposure;

Treated animals in a study of intravenously and subcutaneously acute toxicity, after a single dose of sodium hyaluronate, did not show any signs of toxicity or abnormal behavior or mortality.

RIF. (EFSA Journal 2013;11(6):3260; Hyalgan 20 mg/2 ml solution for injection – intraarticular use Module 2 - CTD Summaries – 2.4 Non Clinical Overview)

based on available data, the classification criteria are not met

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j) aspiration hazard;

Danger not expected because the substance is not a hydrocarbon

based on available data, the classification criteria are not met

12. ECOLOGICAL INFORMATION

12.1 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.

12.5 Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATION

13.1. Waste treatment methods

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

The waste disposal of this product must be carried out in accordance with local laws in force.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

14. TRANSPORT INFORMATION

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

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no data available

15. REGULATORY INFORMATION

There are no additional safety, health or environmental regulations specific to this product.

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 authorization (Annex XIV REACH):

None.

16. OTHER INFORMATION

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)
ICAO:	International Civil Aviation Organization
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
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals

DISCLAIMER OF LIABILITY

The information contained in this document are based on knowledge available at the time of completion, the requirements relating to proper use of the product.

They only refer to the product indicated and constitutes no guarantee, express or implied, regarding its correctness or accuracy.

The user must verify the suitability and completeness of such information in relation to the specific use intended. In case of any unclarity we advise consulting the supplier.

The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

In no event shall Fidia Farmaceutici spa be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Fidia Farmaceutici spa has been advised of the possibility of such damages.

Changes from the previous version:

Sections 3, 7, 9, 10: have been updated.

Section 11: has been updated with data related HYADD4 and sodium hyaluronate.

Section 15: has been updated in accordance with Regulation 1907/2006 (REACH).

This sheet supersedes all previous editions

Safety Data Sheet

according to 1907/2006/EC (REACH), 1272/2008/EC (CLP), and OSHA
GHS

Printing date: 03.20.2020

Revision: 03.20.2020

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

1.1 Product identifier

Trade name: In-Cide v.5

Article number: 100345

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:

Disinfectant

Cleaning agent/ Cleaner

1.3 Details of the supplier of the Safety Data Sheet

Manufacturer/Supplier:

Theochem Laboratories

7373 Rowlett Park Drive

Tampa, FL 33610

Phone: 813-237-6463



1.4 Emergency telephone number:

ChemTel Inc.

(800)255-3924, +1 (813)248-0585

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified as hazardous according to OSHA GHS regulations within the United States.

The product is not classified as hazardous according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

This product does not have a classification according to the CLP regulation.

The product is not classified as hazardous according to OSHA GHS regulations within the United States.

Hazard pictograms Not Regulated

Signal word Not Regulated

Hazard-determining components of labelling: None.

Hazard statements Not Regulated

Precautionary statements Not Regulated.

NFPA ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

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· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **2.3 Other hazards** There are no other hazards not otherwise classified that have been identified.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Components:** None in reportable quantities.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately remove any clothing soiled by the product.
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**
May cause gastro-intestinal irritation if ingested.
Nausea in case of ingestion.
Slight irritant effect on eyes.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
The product is not flammable.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** None.

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- **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.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation

Use personal protective equipment as required.

- **6.2 Environmental precautions** No special measures required.

- **6.3 Methods and material for containment and cleaning up**

Wipe up small spills with paper towel and discard.

For larger spills, add sawdust, chalk or other inert binding material, then sweep up and discard.

- **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**

Use only in well ventilated areas.

Keep out of reach of children.

Avoid breathing mist/vapours/spray.

- **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:**

Store in accordance with local/regional/national/international regulations.

- **Information about storage in one common storage facility:** Store away from foodstuffs.

- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.

- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients 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.

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· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes.

Avoid close or long term contact with the skin.

Wash hands before breaks and at the end of work.

· Respiratory protection:

Not required under normal conditions of use.

For spills, respiratory protection may be advisable.

· Protection of hands:



Protective gloves

Gloves are advised for repeated or prolonged contact.

Wear protective gloves to handle contents of damaged or leaking units.

· Material of gloves Rubber gloves

· Eye protection:



Safety glasses

· Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· Appearance

Form: Liquid

Colour: Blue

· Odour: Pleasant

· Odour threshold: Not determined.

· pH-value: 8,00-11,00

· Melting point/freezing point: Not determined.

· Initial boiling point and boiling range: Not determined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Auto/Self-ignition temperature:

Decomposition temperature: Not determined.

· Explosive properties: Product does not present an explosion hazard.

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· Explosion limits	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	
Relative density:	1,00-1,01
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** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** Reacts with strong acids and oxidising agents.
- **10.4 Conditions to avoid** Avoid acids.
- **10.5 Incompatible materials** Strong acids.
- **10.6 Hazardous decomposition products** Possible in traces.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:** None.
- **Primary irritant effect**
- **Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation:** Based on available data, the classification criteria are not met.
- **Carcinogenic categories**

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

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· NTP (National Toxicology Program):

None of the ingredients are listed.

· OSHA-Ca (Occupational Safety & Health Administration):

None of the ingredients are listed.

· Probable routes of exposure:

Ingestion.
Inhalation
Eye contact.
Skin contact.

· 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.

SECTION 12: Ecological information

· 12.1 Toxicity**· Aquatic toxicity:** No further relevant information available.**· 12.2 Persistence and degradability** Biodegradable**· 12.3 Bioaccumulative potential** Non significant accumulation in organisms**· 12.4 Mobility in soil** No further relevant information available.**· Additional ecological information:****· General notes:**

Due to available data on eliminability/decomposition and bioaccumulation potential, a prolonged damage of the environment is unlikely.

· 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**

Small amounts may be diluted with plenty of water and washed away. Dispose of larger amounts in accordance with Local Authority requirements.

Can be disposed of with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.

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.

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

SECTION 14: Transport information

14.1 UN-Number	
· DOT, ADR, IMDG, IATA	Not Regulated
14.2 UN proper shipping name	
· DOT, ADR, IMDG, IATA	Not Regulated
14.3 Transport hazard class(es)	
· DOT, ADR, 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 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**
- United States (USA)
- SARA
- **Section 355 (extremely hazardous substances):**
- None of the ingredients are listed.
- **Section 313 (Specific toxic chemical listings):**
- None of the ingredients are listed.
- **TSCA (Toxic Substances Control Act):**
- All ingredients are listed.
- **Proposition 65 (California):**

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· 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:**· Carcinogenic Categories****· EPA (Environmental Protection Agency)**

None of the ingredients are listed.

· Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

EPA Product Registration #: 10324-85-9367.

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:

KEEP OUT OF REACH OF CHILDREN**CAUTION**

FIRST AID: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF ON SKIN OR CLOTHING: 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.

IF IN EYES: 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.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass 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.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION. Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using the toilet.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame. Do not mix with oxidizers, anionic soaps and detergents.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Open dumping is prohibited. Store only in original container. Do not reuse empty container. If a leaky container must be contained within another, mark the outer container to identify the contents. Store pesticides away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the

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Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING DISPOSAL: Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides. Triple rinse. After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.

RESIDUE REMOVAL INSTRUCTIONS: Triple rinse container promptly after emptying. Triple rinse as follows: Fill the container 1/4 full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

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

· NIOSH-Ca (National Institute for Occupational Safety and Health)	
None of the ingredients are listed.	
· Canadian Domestic Substances List (DSL)	
All ingredients are listed.	
· Other regulations, limitations and prohibitive 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.

· **Abbreviations and acronyms:**

ADR: 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
 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)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 SVHC: Substances of Very High Concern
 vPvB: very Persistent and very Bioaccumulative
 NIOSH: National Institute for Occupational Safety
 OSHA: Occupational Safety & Health
 LDLo: Lowest Lethal Dose Observed

(Cont'd. on page 10)

Safety Data Sheet
according to 1907/2006/EC (REACH), 1272/2008/EC (CLP), and OSHA
GHS

Printing date: 03.20.2020

Revision: 03.20.2020

Trade name: In-Cide v.5

(Cont'd. from page 9)

Sources

Website, European Chemicals Agency (echa.europa.eu)
Website, US EPA Substance Registry Services (ofmpub.epa.gov/sor_internet/registry/substreg/home/overview/home.do)
Website, Chemical Abstracts Registry, American Chemical Society (www.cas.org)
Patty's Industrial Hygiene, 6th ed., Rose, Vernon, ed. ISBN: 978-0-470-07488-6
Casarett and Doull's Toxicology: The Basic Science of Poisons, 8th Ed., Klaasen, Curtis D., ed., ISBN: 978-0-07-176923-5.
Safety Data Sheets, Individual Manufacturers

SDS Prepared by:
ChemTel Inc.
1305 North Florida Avenue
Tampa, Florida USA 33602-2902
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Website: www.chemtelinc.com

Inactivated Influenza Vaccine



SAFETY DATA SHEET

Page 1 of 5 - Date of Issue: 14 February 2017

IMPORTANT NOTICE This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name	Inactivated Influenza Vaccine
Other Names	All Inactivated Influenza Products manufactured or stored by Seqirus Pty. Ltd. Australia are covered by this Safety Data Sheet.
Use	For the prevention of influenza caused by Influenza Virus, types A and B
Supplier Name	Seqirus Pty Ltd (ABN 26 160 735 035)
Address	63 Poplar Road, Parkville, Victoria 3052, Australia
Telephone	+61 3 9389 2000
Emergency Telephone	+61 3 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as a hazardous chemical according to Australian WHS Regulations

GHS Classification(s)	None Allocated
Signal Word	No Signal Word
Pictogram(s)	No Pictogram(s)
Hazard Statement(s)	None Allocated
Prevention statement(s)	None Allocated
Response	None Allocated
Storage	None Allocated
Disposal	None Allocated

SAFETY DATA SHEET

Inactivated Influenza Vaccine

Page 2 of 5
Date of Issue: 14 February 2017

3. COMPOSITION/INFORMATION ON INGREDIENTS

There are no ingredients in this product that are classified as hazardous and/or no hazardous ingredients above the cut-off GHS percentage.

4. FIRST AID MEASURES

Eye	Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek immediate medical attention.
Swallowed	DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. If sensitive to eggs, seek medical attention immediately.
Skin	Rinse the area with water. If symptoms persist seek medical attention.
Aggravated Medical Conditions	Inactivated Influenza Vaccines are prepared from virus grown in the allantoic cavity of embryonated eggs
Advice to Doctor	Treat symptomatically. Cases of anaphylaxis may require treatment with adrenaline, oxygen, intravenous steroid and airway management including intubation.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard	Not considered a significant fire risk.
Fire Extinguishing Media	No restrictions.
Hazchem Code	None allocated

6. ACCIDENTAL RELEASE MEASURES

Minor Spills	- Wear protective gloves and safety glasses. - Clean up spill immediately using absorbent paper towels. - Place spilled material in clean, dry, sealed container for disposal. - Wash area with copious amounts of water.
Major Spills	- Wear protective gloves and safety glasses. - Contain and absorb spills using earth, sand or inert absorbent. - Collect residues and seal in labelled drums for disposal. - Wash area with copious amounts of water.

7. HANDLING AND STORAGE

- Transport and store at 2 to 8 degrees C (do not freeze).
- Protect from light.
- Store as per Schedule 4 pharmaceutical.

SAFETY DATA SHEET

Inactivated Influenza Vaccine

Page 3 of 5
Date of Issue: 14 February 2017

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards	No exposure limits set by SWA or ACGIH
Engineering Controls	None under normal operating conditions.
Personal Protection	For good infection control, gloves should be worn when administering an injection. The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear to slightly opaque liquid containing some sediment, which readily resuspends upon shaking, in pre-filled syringe with and without attached needle and multi-dose vial
Odour	Odourless
pH	6.9 to 7.4
Boiling Point/Melting Point	Not determined
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	Not determined
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Aqueous solution

10. STABILITY AND REACTIVITY

Reactivity	Not known to be incompatible with any other material.
Stability	Stable under anticipated storage and handling conditions (refer section 7).
Decomposition Products	Not determined

SAFETY DATA SHEET

Inactivated Influenza Vaccine

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Date of Issue: 14 February 2017

11. TOXICOLOGICAL INFORMATION

Eye May cause mild irritation. In hypersensitive individuals, may precipitate an acute allergic reaction. Local Swelling may be accompanied by systemic symptoms. See under Acute Effects, Swallowed.

Ingestion May cause irritation of the gastro-intestinal tract. In hypersensitive individuals, may precipitate an acute allergic reaction.

Symptoms of an allergic reaction may include shortness of breath; swelling of the face, lips, tongue, or other parts of the body; skin rash, itching or hives.

Skin May cause mild irritation.

Inhaled Not an expected route of exposure.

Chronic Health Effects No chronic health effects expected under conditions of use.

12. ECOLOGICAL INFORMATION

- No data available.
- For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.

14. TRANSPORT INFORMATION

Not Classified as a dangerous good by the criteria of the ADG Code

UN Number None allocated

DG Class None allocated

Subsidiary Risk None allocated

Packing Group None allocated

Hazchem Code None allocated

15. REGULATORY INFORMATION

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

SAFETY DATA SHEET**Inactivated Influenza Vaccine**

Page 5 of 5
Date of Issue: 14 February 2017

16. OTHER INFORMATION

Last Revised 14 February 2017

Reason for Revision

- Change SDS Product name as the vaccine is now quadrivalent
- Update Product details
- Update to GHS requirements
- Update Business contact details
- Update Composition and Physical properties information
- Updated NOHSC to SWA

Abbreviations

SWA	- Safe Work Australia
GHS	- Globally Harmonised System
WHS	- Work, Health and Safety
ADG Code	- Australian Dangerous Goods Code
UN Number	- United Nations Number
DG Class	- Dangerous Goods Class
CAS Number	- Chemical Abstract Service Number

Contact Point

Company Contact:	+61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service:	13 11 26
Australian Police, Fire Brigade or Ambulance:	000
New Zealand Poisons Information Centre, 24 hour service:	0800 764 766
New Zealand Police, Fire Brigade or Ambulance:	111

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.

Inactivated Influenza Vaccine



SAFETY DATA SHEET

Page 1 of 5 - Date of Issue: 14 February 2017

IMPORTANT NOTICE This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

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GHS Classification(s)	None Allocated
Signal Word	No Signal Word
Pictogram(s)	No Pictogram(s)
Hazard Statement(s)	None Allocated
Prevention statement(s)	None Allocated
Response	None Allocated
Storage	None Allocated
Disposal	None Allocated

SAFETY DATA SHEET

Inactivated Influenza Vaccine

Page 2 of 5
Date of Issue: 14 February 2017

3. COMPOSITION/INFORMATION ON INGREDIENTS

There are no ingredients in this product that are classified as hazardous and/or no hazardous ingredients above the cut-off GHS percentage.

4. FIRST AID MEASURES

Eye	Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek immediate medical attention.
Swallowed	DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. If sensitive to eggs, seek medical attention immediately.
Skin	Rinse the area with water. If symptoms persist seek medical attention.
Aggravated Medical Conditions	Inactivated Influenza Vaccines are prepared from virus grown in the allantoic cavity of embryonated eggs
Advice to Doctor	Treat symptomatically. Cases of anaphylaxis may require treatment with adrenaline, oxygen, intravenous steroid and airway management including intubation.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard	Not considered a significant fire risk.
Fire Extinguishing Media	No restrictions.
Hazchem Code	None allocated

6. ACCIDENTAL RELEASE MEASURES

Minor Spills	- Wear protective gloves and safety glasses. - Clean up spill immediately using absorbent paper towels. - Place spilled material in clean, dry, sealed container for disposal. - Wash area with copious amounts of water.
Major Spills	- Wear protective gloves and safety glasses. - Contain and absorb spills using earth, sand or inert absorbent. - Collect residues and seal in labelled drums for disposal. - Wash area with copious amounts of water.

7. HANDLING AND STORAGE

- Transport and store at 2 to 8 degrees C (do not freeze).
- Protect from light.
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SAFETY DATA SHEET

Inactivated Influenza Vaccine

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards	No exposure limits set by SWA or ACGIH
Engineering Controls	None under normal operating conditions.
Personal Protection	For good infection control, gloves should be worn when administering an injection. The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear to slightly opaque liquid containing some sediment, which readily resuspends upon shaking, in pre-filled syringe with and without attached needle and multi-dose vial
Odour	Odourless
pH	6.9 to 7.4
Boiling Point/Melting Point	Not determined
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	Not determined
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Aqueous solution

10. STABILITY AND REACTIVITY

Reactivity	Not known to be incompatible with any other material.
Stability	Stable under anticipated storage and handling conditions (refer section 7).
Decomposition Products	Not determined

SAFETY DATA SHEET

Inactivated Influenza Vaccine

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11. TOXICOLOGICAL INFORMATION

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Ingestion May cause irritation of the gastro-intestinal tract. In hypersensitive individuals, may precipitate an acute allergic reaction.

Symptoms of an allergic reaction may include shortness of breath; swelling of the face, lips, tongue, or other parts of the body; skin rash, itching or hives.

Skin May cause mild irritation.

Inhaled Not an expected route of exposure.

Chronic Health Effects No chronic health effects expected under conditions of use.

12. ECOLOGICAL INFORMATION

- No data available.
- For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.

14. TRANSPORT INFORMATION

Not Classified as a dangerous good by the criteria of the ADG Code

UN Number None allocated

DG Class None allocated

Subsidiary Risk None allocated

Packing Group None allocated

Hazchem Code None allocated

15. REGULATORY INFORMATION

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

SAFETY DATA SHEET**Inactivated Influenza Vaccine**

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SAFETY DATA SHEET

Revision date: 24-Oct-2016

Version: 1.0

Page 1 of 8

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: INFLECTRA (infliximab-dyyb) for Injection

Trade Name: INFLECTRA
Synonyms: Infliximab-dyyb
Chemical Family: Recombinant chimeric monoclonal antibody

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
 Pfizer Pharmaceuticals Group
 235 East 42nd Street
 New York, New York 10017
 1-800-879-3477

Pfizer Ltd
 Ramsgate Road
 Sandwich, Kent
 CT13 9NJ
 United Kingdom
 +00 44 (0)1304 616161
 Emergency telephone number:
 International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number:
 CHEMTREC (24 hours): 1-800-424-9300
 Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning
Hazard Statements: May form combustible dust concentrations in air

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

SAFETY DATA SHEET

Material Name: INFLECTRA (infliximab-dyyb) for Injection
Revision date: 24-Oct-2016

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Infliximab	170277-31-3	Not Listed	Not Listed	1

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Disodium Succinate Hexahydrate	6106-21-4	Not Listed	Not Listed	*
Succinic acid	110-15-6	203-740-4	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES**Description of First Aid Measures**

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. It is considered unlikely that, if swallowed, significant amounts of this material would be absorbed into the blood circulation.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:	No data available
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

SAFETY DATA SHEET

Material Name: INFLECTRA (infliximab-dyyb) for Injection
Revision date: 24-Oct-2016

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Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Remove all sources of ignition. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE**Precautions for Safe Handling**

Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control Parameters****Sucrose**

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

SAFETY DATA SHEET

Material Name: INFLECTRA (infliximab-dyyb) for Injection
Revision date: 24-Oct-2016

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

Infliximab

Pfizer Occupational Exposure Band (OEB): B-OEB 3 (control exposure to the range of 100 µg/day to <1,000 µg/day)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Wear impervious gloves (e.g. Nitrile, etc.) as minimum protection. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	White to off-white
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Not applicable	Molecular Weight:	150 KDa

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	5.0 - 7.4
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	

Infliximab

No data available

Disodium Succinate Hexahydrate

No data available

Sucrose

No data available

Succinic acid

No data available

Water for Injection

SAFETY DATA SHEET

Material Name: INFLECTRA (infliximab-dyyb) for Injection
 Revision date: 24-Oct-2016

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Polysorbate 80

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term: As with any protein, the possibility of allergic reactions exists.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include respiratory tract infection, viral illness, hematological effects, skin effects, allergic reaction. Additionally effects on cardiovascular system, gastrointestinal system, musculoskeletal system may occur.

Acute Toxicity: (Species, Route, End Point, Dose)

Infliximab

Rat Intravenous NOAEL 50 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

SAFETY DATA SHEET

Material Name: INFLECTRA (infliximab-dyyb) for Injection
Revision date: 24-Oct-2016

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11. TOXICOLOGICAL INFORMATION

Infliximab

2 Week(s)	Rat	Intravenous	50 mg/kg (3 doses)	NOAEL	None identified
6 Month(s)	Mouse	Intravenous	40 mg/kg/day	NOAEL	None identified

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Infliximab

<i>In Vivo</i> Micronucleus	Mouse	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative

Sucrose

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transportation as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

SAFETY DATA SHEET

Material Name: INFLECTRA (infliximab-dyyb) for Injection
Revision date: 24-Oct-2016

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Infliximab

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Disodium Succinate Hexahydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Succinic acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-740-4

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

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Material Name: INFLECTRA (infliximab-dyyb) for Injection
Revision date: 24-Oct-2016

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Version: 1.0

15. REGULATORY INFORMATION**16. OTHER INFORMATION**

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Revision date: 24-Oct-2016
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET



Infliximab Formulation

Version Revision Date: SDS Number: Date of last issue: 04/24/2019
7.1 09/13/2019 19289-00015 Date of first issue: 10/07/2014

SECTION 1. IDENTIFICATION

Product name : Infliximab Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 70 - < 90
Infliximab	170277-31-3	>= 10 - < 20

Actual concentration is withheld as a trade secret

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.

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In case of eye contact	:	Get medical attention if symptoms occur. If in eyes, rinse well with water.
If swallowed	:	Get medical attention if irritation develops and persists. 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	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. 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	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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. 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	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on

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surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust causing an explosion.
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Minimize dust generation and accumulation.
 Keep container closed when not in use.
 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.
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Infliximab	170277-31-3	TWA	150 µg/m ³	Internal

- Engineering measures : Ensure adequate ventilation, especially in confined areas.
 Minimize workplace exposure concentrations.
 Apply measures to prevent dust explosions.
 Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are

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designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

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 : Chemical-resistant gloves

Remarks : For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment: Safety goggles

Skin and body protection : Skin should be washed after contact.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers 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 : Amorphous powder

Color : white

Odor : No data available

Odor Threshold : No data available

pH : 7.2

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Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm ³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing,

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tions	handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
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.

Components:

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Infliximab:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Infliximab:

Remarks : No data available

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Sucrose:

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Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Infliximab:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosomal aberration
Test system: human lymphoblastoid cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Method: OECD Test Guideline 474
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

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 component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

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.

Components:**Infliximab:**

Effects on fertility : Test Type: Fertility
Species: Mouse
Application Route: Intravenous injection
Fertility: NOAEL: 40 mg/kg body weight
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse, female
Application Route: Intravenous injection
Duration of Single Treatment: 6 - 12 d
General Toxicity Maternal: NOAEL: 40 mg/kg body weight
Teratogenicity: NOAEL F1: 40 mg/kg body weight
Developmental Toxicity: NOAEL F1: 40
Embryo-fetal toxicity.: NOAEL: 40 mg/kg body weight
Remarks: Based on data from similar materials

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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Infliximab:**

Species	:	Mouse
NOAEL	:	40 mg/kg
Application Route	:	Intravenous
Exposure time	:	6 Months
Number of exposures	:	daily

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Infliximab:**

Inhalation	:	Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea, Fatigue, Headache, Back pain

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Infliximab:****Ecotoxicology Assessment**

Acute aquatic toxicity	:	No data available

Chronic aquatic toxicity	:	No data available

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Sucrose:**

Partition coefficient: n-octanol/water	:	Pow: < 1

Mobility in soil

No data available

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Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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**

Not regulated as a dangerous good

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 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Pennsylvania Right To Know**

Sucrose

57-50-1

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Infliximab

170277-31-3

California Permissible Exposure Limits for Chemical Contaminants

Sucrose

57-50-1

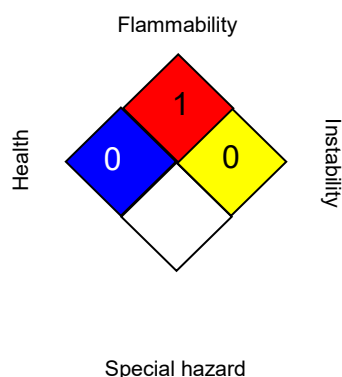
The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
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
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC

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- International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 : 09/13/2019

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



SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Ketorolac Tromethamine Injection, USP
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: January 08, 2009
SDS Revision Date: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Flammable Liquid. Category 2.
 Serious Eye Damage. Category 1.
 Respiratory sensitisation. Category 1.
 Skin Irritation. Category 2.
 Skin Sensitization. Category 1.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements: Highly flammable liquid and vapor.
 Causes serious eye damage.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Causes skin irritation.
 May cause an allergic skin reaction.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 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.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 In case of inadequate ventilation wear respiratory protection.
 IF ON SKIN: Wash with plenty of water.
 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical advice/attention.
 Immediately call a POISON CENTER or doctor/physician.
 Specific treatment (see ... on this label).
 If skin irritation occurs: Get medical advice/attention.
 If skin irritation or rash occurs: Get medical advice/attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 In case of fire: Use dry chemical, carbon dioxide to extinguish small fires. Use water for large fires.
 Store in a well-ventilated place. Keep cool.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Adverse reactions from therapeutic doses include: edema, hypertension, pruritus, rash, nausea, dyspepsia, gastrointestinal pain, diarrhea, constipation, flatulence, gastrointestinal fullness, vomiting, stomatitis, purpura, headache, drowsiness, dizziness, and sweating. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with active peptic ulcer disease, gastrointestinal bleeding or perforation, history of peptic ulcer diseases, gastrointestinal bleeding, advanced renal impairment or at risk for renal failure due to volume depletion, hypersensitivity to ketorolac tromethamine, allergic manifestations to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs), and those with medical conditions that are at high risk for bleeding.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Ketorolac Tromethamine	74103-06-3	15 mg/mL, 30 mg/mL, or 60 mg/2 mL	
Citric Acid, Anhydrous	77-92-9	0.1 %	
Sodium Chloride	7647-14-5	See package insert	
Ethyl Alcohol	64-17-5	Amount: 10% % Amount: 10% by weight Amount: 10% by Volume	
Water for Injection	7732-18-5	Quantity Sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flammable Properties:	Flammable.
Flash Point:	109 °F (43 °C)
Flash Point Method:	closed cup.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	3.3% as ethanol
Upper Flammable/Explosive Limit:	19% as ethanol
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

shower.

Hygiene Practices:

Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Ethyl Alcohol:

Guideline OSHA: PEL-TWA: 1000 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Pale Yellow light amber
Boiling Point:	Not established.
Melting Point:	153 - 155 °C
Solubility:	Not applicable.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.2 - 7.6
Molecular Formula:	Mixture
Molecular Weight:	376.41
Flash Point:	109 °F (43 °C)
Flash Point Method:	closed cup.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Avoid storage near oxidizers and water reactive materials.

SECTION 11 : TOXICOLOGICAL INFORMATION

Ketorolac Tromethamine :

Acute Toxicity: LD50: IP Mouse 225 mg/kg

Ketorolac Tromethamine :

RTECS Number: UY7759800

Ingestion: Oral - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Human TDLo: 0.14 mg/kg [Behavioral - analgesia]
Subcutaneous - Mouse TDLo: 0.3 mg/kg [Behavioral - analgesia]
Intraperitoneal. - Mouse LDLo: 100 mg/kg [Details of toxic effects not reported other than lethal dose value]

Citric Acid, Anhydrous :

RTECS Number: GE7350000

Eye:	Eye - Rabbit Standard Draize test.: 750 ug/24H [severe]
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Ingestion:	Oral - Rat LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 5040 mg/kg [Lungs, Thorax, or Respiration - Other changes Musculoskeletal - Other changes] Oral - Mouse LD50: 7280 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 42 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands] Intravenous. - Rabbit LD50: 330 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands] Subcutaneous - Rat LD50: 5500 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes] Subcutaneous - Mouse LD50: 2700 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes] Intraperitoneal. - Rat LD50: 290 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 903 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD16: 197 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD: 382 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Chloride :

RTECS Number:	VZ4725000
Eye:	Eye - Rabbit Standard Draize test.: 10 mg [Moderate]
Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Inhalation:	Inhalation - Rat LC50: >42 gm/m ³ /1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes] Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability] Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion] Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral] Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

Ethyl Alcohol :

RTECS Number:	KQ6300000
Eye:	Eye - Rabbit Rinsed with water.: 100 mg/4S
Skin:	Administration onto the skin - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Open irritation test: 400 mg Administration onto the skin - Rabbit Standard Draize test.: 20 mg/24H
Inhalation:	Inhalation - Rat LC50: 20000 ppm/10H [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 39 gm/m ³ /4H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Rat LD50: 7060 mg/kg [Lungs, Thorax, or Respiration - Other changes] Oral - Mouse LD50: 3450 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 7 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Human TDLo: 1.6 gm/kg/6H [Biochemical - Metabolism (Intermediary) - other] Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep] Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep Behavioral - tolerance] Intravenous. - Rat LD50: 1440 mg/kg [Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Rabbit LD50: 2374 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 0.5 gm/kg [Brain and Coverings - recordings from specific areas of CNS] Intravenous. - Human TDLo: 0.89 mL/kg [Vascular - regional or general arteriolar constriction Vascular - measurement of regional blood flow] Intravenous. - Mouse LD50: 1973 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic]

structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - musculoskeletal system]

Intravenous. - Rat TDLo: 3 gm/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]

Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]

Intravenous. - Rabbit TDLo: 15 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - other effects to embryo]

Subcutaneous - Mouse LD50: 8285 mg/kg [Details of toxic effects not reported other than lethal dose value]

Subcutaneous - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]

Subcutaneous - Mouse TDLo: 5 gm/kg [Liver - hepatitis (hepatocellular necrosis), zonal]

Intraperitoneal. - Rat TDLo: 3000 mg/kg [Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 3500 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - dehydrogenases]

Intraperitoneal. - Rat TDLo: 1000 mg/kg [Brain and Coverings - other degenerative changes Liver - other changes Biochemical - Metabolism (Intermediary) - lipids including transport]

Intraperitoneal. - Rat TDLo: 0.25 gm/kg [Behavioral - alteration of operant conditioning]

Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 1.5 mg/kg [Behavioral - antianxiety]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 2.5 gm/kg [Behavioral - somnolence (general depressed activity) Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - somnolence (general depressed activity)]

Intraperitoneal. - Mouse TDLo: 2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 1 gm/kg [Behavioral - antianxiety Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 1000 mg/kg [Liver - other changes]

Intraperitoneal. - Mouse TDLo: 0.25 gm/kg [Behavioral - analgesia]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - food intake (animal)]

Intraperitoneal. - Rat LD50: 3600 ug/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Mouse LD50: 528 mg/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Rabbit LD50: 963 mg/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Guinea pig LD50: 3414 mg/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Mouse TDLo: 4.2 gm/kg [Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 2.45 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]

Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 1.75 gm/kg [Behavioral - ataxia]

Intraperitoneal. - Mouse TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Rat TDLo: 3000 mg/kg [Behavioral - sleep]

Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Endocrine - differential effect of sex or castration on observed toxicity Biochemical - Metabolism (Intermediary) - other]

Intraperitoneal. - Rat TDLo: 1 gm/kg [Sense Organs and Special Senses (Taste) - change in function]

Intraperitoneal. - Mouse TDLo: 4.25 gm/kg [Behavioral - sleep]

Intraperitoneal. - Rat TDLo: 2.4 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]

Intraperitoneal. - Mouse TDLo: 2 mg/kg [Brain and Coverings - recordings from specific areas of CNS]

Intraperitoneal. - Rat TDLo: 1.5 gm/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]

Intraperitoneal. - Rat TDLo: 1.25 mg/kg [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Mouse LDLo: 4000 mg/kg [Behavioral - alteration of classical conditioning Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 2700 mg/kg [Behavioral - ataxia]

Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - analgesia]

Intraperitoneal. - Rat TDLo: 2000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - other]

Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - withdrawal]

Intraperitoneal. - Mouse TDLo: 2.0 gm/kg [Behavioral - ataxia Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphokinase]

Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - muscle weakness]

Intraperitoneal. - Rat TDLo: 2000 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - ataxia Behavioral - alteration of operant conditioning]

Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Rat TDLo: 3000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)]

Intraperitoneal. - Mouse TDLo: 1.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - ataxia Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 3.5 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]

Intraperitoneal. - Mouse TDLo: 0.3 mg/kg [Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 1.2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 1.8 mg/kg [Behavioral - alteration of classical conditioning Behavioral - antianxiety Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 4 gm/kg/8D (intermittent) [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 4.8 mg/kg/4D (intermittent) [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Mouse TDLo: 12 mg/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests Nutritional and Gross Metabolic - weight loss or decreased weight gain]

Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - tolerance Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 3 gm/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 37.8 mg/kg/21D (intermittent) [Behavioral - changes in motor activity (specific assay) Behavioral - tolerance Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 12.6 mg/kg/21D (intermittent) [Behavioral - tolerance]

Intraperitoneal. - Rat Mutation test systems not otherwise specified: 250 gm/kg/16D (continuous)

Intraperitoneal. - Mouse Micronucleus test: 1240 mg/kg/2D

Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Effects on Newborn - behavioral Reproductive - Effects on Newborn - physical]

Intraperitoneal. - Rat TDLo: 2240 mg/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)]
 Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
 Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
 Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Rat TDLo: 3600 mg/kg [Reproductive - Effects on Newborn - behavioral]
 Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
 Intraperitoneal. - Mouse TDLo: 5622 ug/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Mouse TDLo: 4 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
 Intraperitoneal. - Mouse TDLo: 4300 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
 Intraperitoneal. - Mouse TDLo: 2.9 gm/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
 Intraperitoneal. - Rat TDLo: 11.25 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
 Intraperitoneal. - Mouse TDLo: 15 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - eye/ear]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
 Intraperitoneal. - Mouse TDLo: 5.8 gm/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Non regulated.
IATA UN Number:	Non regulated.

SECTION 15 : REGULATORY INFORMATION

Citric Acid, Anhydrous :

TSCA Inventory Status:	Listed
EINECS Number:	201-069-1
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

Sodium Chloride :

TSCA Inventory Status:	Listed
EINECS Number:	231-598-3
Canada DSL:	Listed

Ethyl Alcohol :

TSCA Inventory Status:	Listed
EINECS Number:	200-578-6

Canada DSL: Listed
Canada IDL: : 3300 ppm
Water for Injection :
TSCA Inventory Status: Listed
Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 2
HMIS Fire Hazard: 3
HMIS Reactivity: 1
HMIS Personal Protection: M

SDS Creation Date: January 08, 2009

SDS Revision Date: June 01, 2015

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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1. Product and Company Identification

PRODUCT NAME: KEVZARATM (sarilumab) 150 mg/1.14 mL and 200 mg/1.14 mL

Substance name: Sarilumab

Synonyms: SAR153191; REGN88

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 product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification: Not classified as a hazardous substance or mixture.

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, sarilumab:

Signal Word: None required.

Hazard Statement(s): None required.

Symbol(s): None required.

Precautionary Statement(s):

- Prevention: None required.
- Response: None required.
- Storage: None required.
- Disposal: None required.

2.3 Hazards Not Otherwise Classified (HNOC)

None known.

3. Composition/Information on Ingredients

Product description: Sarilumab, a recombinant human monoclonal antibody, in aqueous buffered solution.

<u>Chemical Name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
Sarilumab	Sarilumab	Not available	150 mg/1.14 mL and 200 mg/1.14 mL
α -D-Glucopyranosyl β -D-fructofuranoside	Sucrose	57-50-1	5 % w/v
Polyoxyethylene 20 sorbitan monolaurate	Polysorbate 20	9005-64-5	0.2 % w/v
L-Histidine	Histidine	71-00-1	25 mM
L-Arginine	Arginine	74-79-3	50 mM

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 if irritation develops.

Skin contact: In case of contact with product, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician. 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.

4.2 Most important symptoms and effects, both acute and delayed

Based on the sarilumab clinical development program, the anticipated adverse events for sarilumab are neutropenia, thrombocytopenia, elevation in liver transaminases, elevation in lipids and infections, all of which are consistent with the pharmaceutical effect of IL-6 inhibition. Dose administration was by subcutaneous injection.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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

This product presents a minimal fire or explosion hazard. Hazardous combustion products could include: 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

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash hands thoroughly after handling.

7.2 Conditions for Safe Storage

Store at 36° to 46° F (2°C to 8°C).

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit: not established.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions. Use of a laboratory hood or biosafety cabinet is advised when the generation of aerosols is possible.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses with side shields 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

Appearance: colorless liquid.

Odor: no detectable odor.

Odor threshold: no data available.

pH: 6.0

Melting point/ Freezing point: no data available.

Initial boiling point/boiling point range: no data available.

Flash point: not applicable.

Evaporation rate: similar to water.

Flammability: no data available.

Upper/lower flammability or explosive limits: no data available.

Vapor pressure: similar to water.

Vapor density: no data available.

Relative density: 1.047 - 1.072

Solubility: Miscible with water.
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 sarilumab 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. As an antibody, exposure by the oral route is likely negligible.

Symptoms related to the physical, chemical and toxicological characteristics: Based on the sarilumab clinical development program, the anticipated adverse events for sarilumab are neutropenia, thrombocytopenia, elevation in liver transaminases, elevation in lipids and infections, all of which are consistent with the pharmaceutical effect of IL-6 inhibition. Dose administration was by subcutaneous injection.

Effects of short-term (acute) exposure: No data available. No adverse effects were observed in repeat-dose animal studies.

Effects of long-term (chronic) exposure: No adverse effects were observed in repeat-dose animal studies.

Acute toxicity (LD₅₀): Single-dose acute toxicology studies were not performed.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available. No adverse effects were observed in repeat-dose animal studies.

Specific target organ toxicity – repeated exposure (STOT-RE): No adverse effects were observed in repeat-dose animal studies.

Carcinogenicity: No long-term animal studies have been performed to establish the carcinogenicity potential of sarilumab.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: No teratogenic effects or adverse effects on fertility were observed in several animal studies.

Mutagenicity: Mutagenicity studies have not been conducted. These studies are not usually conducted for monoclonal antibodies.

Aspiration hazard: No data available.

12. Ecological Information

The following information is for the active ingredient sarilumab unless otherwise noted:

12.1. Ecotoxicity

No data available.

12.2. Persistence and degradability

No data available. Because sarilumab is a protein, it is expected to degrade to small peptides and individual amino acids.

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.

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

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

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.

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%

mM: Millimolar

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: July 21, 2016; First version.



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KRYSTEXXA® (pegloticase)
SAFETY DATA SHEET

1. IDENTIFICATION	
Product name:	KRYSTEXXA® (pegloticase)
CAS No:	885051-90-1
NDC:	54396-801-01 or 60809-801-01
Emergency number:	1-888-KRYSTEXXA (1-888-579-7839)
Company name:	Crealta Pharmaceuticals LLC
Company address:	500 W. Silver Spring Drive, Suite K-200 Glendale, WI 53217

2. HAZARD(S) IDENTIFICATION	
Physical / Chemical Hazards	No physical or chemical hazards have been reported or are known.
Human health hazards	This is a recombinant protein. There are no known health hazards associated with the material and no adverse health effects are expected upon contact. The material is non-hazardous, non-infectious, non-contagious, non-toxic, and non-irritating by handling.
Environmental hazards	No environmental hazards have been reported or are known.

3. COMPOSITION / INFORMATION ON INGREDIENTS	
Ingredient	
PEGylated uricase, purified recombinant protein (enzyme), urate oxidase. The total molecular weight of pegloticase is ~545 kDa.	
Sodium phosphate	
Sodium chloride	



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4. FIRST - AID MEASURES	
Inhalation	Fresh air.
Ingestion	Drink water.
Skin contact	Wash off with water.
Eye contact	Flush with water after contact with the eye.

5. FIRE-FIGHTING MEASURES
This product is non-combustible. There are no special risks.

6. ACCIDENTAL RELEASE MEASURES
There are no special risks; dry the area of the spill.

7. HANDLING AND STORAGE
The product should be stored closed. May be stored between 2° - 8° Celsius. Do not freeze. Use gloves and eye protection when handling.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION
Gloves, goggles, or other types of protective equipment are recommended required.

9. PHYSICAL AND CHEMICAL PROPERTIES
A colorless to slightly opalescent, odorless liquid.

10. STABILITY AND REACTIVITY
The product is stable for 3 years when stored according to recommendations.



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11. TOXICOLOGICAL INFORMATION

No significant pathology or toxic effects were seen in animal or studies.
 Hazardous properties are improbable.

12. ECOLOGICAL INFORMATION

No ecological problems are to be expected.

13. DISPOSAL CONSIDERATIONS

Product: Disposal following applicable local, state and federal regulations.

Packaging: Disposal in compliance with applicable local, state and federal regulations. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

14. TRANSPORT INFORMATION.

Ship and store 2-8°C

15. REGULATORY INFORMATION

Labeling according to applicable regulations.

16. OTHER INFORMATION

Date of issue: September 23rd, 2014

Date Revised: July 8th, 2015

Disclaimer:

The information and recommendation contained herein are based upon tests believed to be reliable. However, Crealta Pharmaceuticals LLC does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage maybe required. Crealta Pharmaceuticals LLC assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

End of Safety Data Sheet



SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Lidocaine hydrochloride and epinephrine injection, solution (Hospira, Inc.)

Trade Name: Not established
Synonyms: Lignocaine with epinephrine
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product anesthetic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
 275 North Field Drive
 Lake Forest, Illinois 60045
 1-800-879-3477

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Epinephrine	51-43-4	200-098-7	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	<= 0.002
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Lidocaine Hydrochloride	73-78-9	200-803-8	Acute Tox.4 (H302)	<= 2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
Sodium metabisulfite USP	7681-57-4	231-673-0	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES**Description of First Aid Measures**

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

7. HANDLING AND STORAGE**Precautions for Safe Handling**

Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
SODIUM HYDROXIDE	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

Sodium metabisulfite USP

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Denmark OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	5 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Switzerland OEL - TWAs	5 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Epinephrine

Pfizer Occupational Exposure Band (OEB): OEB 4 - Skin (control exposure to the range of 1ug/m³ to <10ug/m³, provide additional precautions to protect from skin contact)

Lidocaine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Sodium chloride

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Water for injection

No data available

Sodium chloride

No data available

Sodium metabisulfite USP

No data available

SODIUM HYDROXIDE

No data available

HYDROCHLORIC ACID

No data available

Epinephrine

No data available

Lidocaine Hydrochloride

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	

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10. STABILITY AND REACTIVITY

Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION**Information on Toxicological Effects****General Information:**

There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term:

Harmful if swallowed. May cause mild eye irritation. May cause slight skin irritation. (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects:

Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

Acute Toxicity: (Species, Route, End Point, Dose)**Sodium chloride**

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Epinephrine

Rat Dermal LD50 62 mg/kg
Rat Oral LD50 30mg/kg

Lidocaine Hydrochloride

Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25mg/kg
Rat Intraperitoneal LD50 133mg/kg
Mouse Oral LD50 292mg/kg
Mouse Intravenous LD50 19.5mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)**Sodium chloride**

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Lidocaine Hydrochloride

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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11. TOXICOLOGICAL INFORMATION

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**Epinephrine**

Embryo / Fetal Development	Rat	Intravenous	Dose not specified	Not teratogenic	
Embryo / Fetal Development	Rabbit	Subcutaneous	30 times human dose	LOAEL	Developmental toxicity
Embryo / Fetal Development	Mouse	Subcutaneous	7 times human dose	LOAEL	Developmental toxicity

Lidocaine Hydrochloride

Embryo / Fetal Development	Rat	Subcutaneous	30 mg/kg	NOAEL	Not teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	56 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	72 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intravenous	500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	6 mg/kg	LOAEL	Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**HYDROCHLORIC ACID**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

Epinephrine

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Sister Chromatid Exchange	Negative with activation	
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Equivocal without activation

Lidocaine Hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Sodium metabisulfite USP

IARC:	Group 3 (Not Classifiable)

HYDROCHLORIC ACID

IARC:	Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:	No data available

Persistence and Degradability:	No data available

Bio-accumulative Potential:	No data available

Mobility in Soil:	No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Epinephrine

RCRA - P Series Wastes

Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Epinephrine

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-098-7

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg

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15. REGULATORY INFORMATION

CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6
	231-595-7
Lidocaine Hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-803-8
Sodium chloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
SODIUM HYDROXIDE	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5
Sodium metabisulfite USP	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	
	231-673-0
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	
	231-791-2

SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine
injection, solution (Hospira, Inc.)
Revision date: 27-Jul-2017

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15. REGULATORY INFORMATION**16. OTHER INFORMATION****Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Acute toxicity, oral-Cat.3; H302 - Harmful if swallowed
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: New data sheet.

Revision date: 27-Jul-2017

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

SAFETY DATA SHEET

Lysol Brand II Kills 99.9% of Viruses & Bacteria** Disinfecting Wipes
Crisp Linen Scent, Citrus Meadows Scent, Lemon & Lime Blossom Scent, Lemon
Scent, Ocean Fresh Scent, Fresh Scent



1. Product and company identification

Product name : Lysol Brand II Kills 99.9% of Viruses & Bacteria** Disinfecting Wipes
Crisp Linen Scent, Citrus Meadows Scent, Lemon & Lime Blossom Scent, Lemon Scent,
Ocean Fresh Scent, Fresh Scent

Distributed by : Reckitt Benckiser LLC.
Morris Corporate Center IV
399 Interpace Parkway (P.O. Box 225)
Parsippany, New Jersey 07054-0225
+1 973 404 2600

Emergency telephone number (Medical) : 1-800-338-6167

Emergency telephone number (Transport) : 1-800-424-9300 (U.S. & Canada) CHEMTREC
Outside U.S. and Canada (North America), call Chemtrec:703-527-3887

Website: : <http://www.rbnainfo.com>

Product use : Surface Disinfectant.

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS # : D8169502 v6.0

Formulation #: : Lysol Brand II Kills 99.9% of Viruses & Bacteria** Disinfecting Wipes
- Crisp Linen Scent
- Citrus Meadows Scent
- Lemon & Lime Blossom Scent
- Lemon Scent
- Ocean Fresh Scent
- Fresh Scent

EPA ID No. : 777-114

UPC Code / Sizes : Wipe impregnated with liquid (Loading ratio 4:1 (premix:wipe) / 35, 80 and 110 count wipe in HDPE canister)

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

2. Hazards identification

Classification of the substance or mixture : Not classified

GHS label elements

Hazard pictograms : Not applicable.

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : None known.

Hazards not otherwise classified : None known.

3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
Ethyl alcohol	1 - 2.5	64-17-5

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional 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.

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 : May cause eye irritation upon direct contact with eyes.

Inhalation : No known significant effects or critical hazards.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

4. First aid measures

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)

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

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.

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).

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

6. Accidental release measures

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.

7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- 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.

8. Exposure controls/personal protection

Control

Occupational exposure limits

Ingredient name	Exposure limits
Ethyl alcohol	ACGIH TLV (United States, 4/2014). STEL: 1000 ppm 15 minutes. OSHA PEL 1989 (United States, 3/1989). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 2/2013). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.

- 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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

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.

9. Physical and chemical properties

Appearance

- Physical state** : Solid. [Presaturated Wipes]
- Color** : Clear.
- Odor** : Characteristic.
- Odor threshold** : Not available.
- pH** : 10.5 [liquid preparations]
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Closed cup: >93.3°C (>199.9°F) liquid preparations
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : 0.999 [liquid preparations]
- Solubility** : Easily soluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

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.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethyl alcohol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
*Lysol Disinfecting Wipes	LD50 Oral	Rat	7 g/kg	-
	LC50 Inhalation Vapor	Rat	>2.04 mg/l	24 hours
	LD50 Dermal	Rat	>5000 mg/kg	-
	LD50 Oral	Rat	>5000 mg/kg	-

Conclusion/Summary : Not classified Harmful. *Information is based on toxicity test result of the concentrate of a similar product.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethyl alcohol	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes	-
*Lysol Disinfecting Wipes	Eyes - Mild irritant	Rabbit	-	100 milligrams	-
	Eyes - Moderate irritant	Rabbit	-	24 hours 500 milligrams	-
	Eyes - Severe irritant	Rabbit	-	100 microliters	-
	Skin - Mild irritant	Rabbit	-	500 milligrams	-
	Skin - Moderate irritant	Rabbit	-	400 milligrams	-
	Skin - Slight irritant	Rabbit	1.2	24 hours 20 milligrams	-
	Eyes - Cornea opacity	Rabbit	0	-	-

Conclusion/Summary

Skin	: Slightly irritating to the skin. *Information is based on toxicity test result of the concentrate of a similar product.
Eyes	: Moderately irritating to eyes. *Information is based on toxicity test result of the concentrate of a similar product.

Sensitization

Product/ingredient name	Route of exposure	Species	Result
*Lysol Disinfecting Wipes	skin	Guinea pig	Not sensitizing

Conclusion/Summary

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

11. Toxicological information

Skin : Non-sensitizer to skin. *Information is based on toxicity test result of the concentrate of a similar product.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
Ethyl alcohol	-	1	-

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 : May cause eye irritation upon direct contact with eyes.
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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

11. Toxicological information

Potential delayed effects : Not available.

Potential chronic health effects

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.

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethyl alcohol	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franciscana - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC 4.995 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 0.375 ul/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks

Persistence and degradability

Not available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethyl alcohol	-0.35	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

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.

14. Transport information

Not a DOT controlled material (United States). Not a TDG-controlled material. This preparation is not classified as dangerous according to international transport regulations (ADR/RID, IMDG or ICAO/IATA).

15. Regulatory information

U.S. Federal regulations : **TSCA 4(a) proposed test rules:** Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides
TSCA 8(a) PAIR: 2-methylpropan-2-ol; nonanal; decanal; 3-p-cumenyl-2-methylpropionaldehyde; octanal; dodecanal; 2-(4-tert-butylbenzyl)propionaldehyde; α -hexylcinnamaldehyde
TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): All components are listed or exempted.

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

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Ethyl alcohol	1 - 2.5	Yes.	No.	No.	Yes.	No.

Code # : D8169502_US

SDS # : D8169502 v6.0

Date of issue : 5/26/2016

9/11

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

15. Regulatory information

State regulations

- Massachusetts** : The following components are listed: ETHYL ALCOHOL
New York : None of the components are listed.
New Jersey : The following components are listed: ETHYL ALCOHOL; ALCOHOL
Pennsylvania : The following components are listed: DENATURED ALCOHOL

Canada

- WHMIS (Canada)** : Not controlled under WHMIS (Canada).

Canadian lists

- Canadian NPRI** : The following components are listed: Ethanol
CEPA Toxic substances : None of the components are listed.
Canada inventory : All components are listed or exempted.

Label elements

- Signal word:** : CAUTION
Hazard statements : May cause eye irritation.
Precautionary measures : Avoid contact with eyes. Wash hands after use.
 Keep out of reach of children.

16. Other information

Hazardous Material Information System (U.S.A.) :

Health	1
Flammability	1
Physical hazards	0
Personal protection	B

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) :



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Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D8169502 v6.0

16. Other information

Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

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

Date of issue : 5/26/2016
Date of previous issue : 03/07/2014.
Version : 6
Prepared by : Reckitt Benckiser LLC.
 Product Safety Department
 1 Philips Parkway
 Montvale, New Jersey 07646-1810 USA.
 FAX: 201-476-7770

Revision comments : Update as per US GHS.

▣ Indicates information that has changed from previously issued version.

Notice to reader

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.



RB is a member of the CSPA Product Care Product Stewardship Program.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

SAFETY DATA SHEET

LYSOL® All Purpose Cleaner - Power White & Shine Trigger with Bleach



1. Product and company identification

Product name : LYSOL® All Purpose Cleaner - Power White & Shine Trigger with Bleach

Distributed by : Reckitt Benckiser LLC.
Morris Corporate Center IV
399 Interpace Parkway (P.O. Box 225)
Parsippany, New Jersey 07054-0225
+1 973 404 2600

Emergency telephone number (Medical) : 1-800-338-6167

Emergency telephone number (Transport) : 1-800-424-9300 (U.S. & Canada) CHEMTREC
Outside U.S. and Canada (North America), call Chemtrec:703-527-3887

Website: : <http://www.rbnainfo.com>

Product use : Multipurpose Cleaner

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS # : D0004478 v5.0

Formulation #: : 292-017A (0003419 v4.0)

EPA ID No. : 777-83

UPC Code / Sizes : 19200-78915-30 (32 oz. Trigger HDPE Bottle)

2. Hazards identification

Classification of the substance or mixture : CORROSIVE TO METALS - Category 1
SKIN CORROSION/IRRITATION - Category 2
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2B
SKIN SENSITIZATION - Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : May be corrosive to metals.
Causes skin and eye irritation.
May cause an allergic skin reaction.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0004478 v5.0

2. Hazards identification

Precautionary statements

- General** : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
- Prevention** : Wear protective gloves. Wear eye or face protection. Keep only in original container. Avoid breathing vapor. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.
- Response** : Absorb spillage to prevent material damage. IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical 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 attention.
- Storage** : Store in corrosive resistant container with a resistant inner liner.
- Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Supplemental label elements** : None known.
- Hazards not otherwise classified** : None known.

3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
sodium hypochlorite, solution	1 - 2.5	7681-52-9
sodium hydroxide	< 0.25	1310-73-2

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional 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.

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. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0004478 v5.0

4. First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. 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. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation. May cause an allergic skin reaction.
- Ingestion** : Irritating to mouth, throat and stomach.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- 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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : In a fire or if heated, a pressure increase will occur and the container may burst.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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5. Fire-fighting measures

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
halogenated compounds
metal oxide/oxides
- 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.

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. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Absorb spillage to prevent material damage. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Absorb spillage to prevent material damage. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. 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.

7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Keep away from acids. Empty containers retain product residue and can be hazardous. Do not reuse container. Absorb spillage to prevent material damage.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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7. Handling and storage

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. Store in corrosive resistant container with a resistant inner liner. Separate from acids. 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.

8. Exposure controls/personal protection

Control

Occupational exposure limits

Ingredient name	Exposure limits
sodium hypochlorite, solution	AIHA WEEL (United States, 10/2011). STEL: 2 mg/m ³ 15 minutes.
sodium hydroxide	ACGIH TLV (United States, 6/2013). C: 2 mg/m ³ OSHA PEL 1989 (United States, 3/1989). CEIL: 2 mg/m ³ NIOSH REL (United States, 10/2013). CEIL: 2 mg/m ³ OSHA PEL (United States, 2/2013). TWA: 2 mg/m ³ 8 hours.

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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

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: chemical splash goggles.

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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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8. Exposure controls/personal protection

- 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, 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.

9. Physical and chemical properties

Appearance

Physical state : Liquid. [Clear.]

Color : Straw. [Light]

Odor : Characteristic.

Odor threshold : Not available.

pH : 12.3 to 12.7 [Conc. (% w/w): 100%][25°C]

Melting point : Not available.

Boiling point : Not available.

Flash point : Closed cup: >93.3°C (>199.9°F)

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : 1.042 to 1.048@ 20°C

Solubility : Easily soluble in the following materials: cold water and hot water.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

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 : Reactive or incompatible with the following materials:
acids
Do not mix with household chemicals.
May be corrosive to metals.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
*LYSOL® All Purpose Cleaner - Power White & Shine Trigger with Bleach	LC50 Inhalation Vapor	Rat	200 mg/l	4 hours
	LD50 Dermal	Rat	>5000 mg/kg	-
	LD50 Oral	Rat	>5000 mg/kg	-

Conclusion/Summary : Not classified Harmful. * Information is based on toxicity test result of a similar product.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium hydroxide	Eyes - Severe irritant	Monkey	-	24 hours 1 Percent	-
	Eyes - Mild irritant	Rabbit	-	400 Micrograms	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 Micrograms	-
	Eyes - Severe irritant	Rabbit	-	1 Percent	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 milligrams	-
	Skin - Mild irritant	Human	-	24 hours 2 Percent	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 milligrams	-
sodium hypochlorite, solution	Eyes - Mild irritant	Rabbit	-	1.31 milligrams	-
*LYSOL® All Purpose Cleaner - Power White & Shine Trigger with Bleach	Eyes - Moderate irritant	Rabbit	-	10 milligrams	-
	Eyes - Iris lesion	Rat	>1	-	-
	Skin - Erythema/Eschar	Rat	5.25	-	-

Conclusion/Summary

Skin : Severely irritating to the skin. *Information is based on toxicity test result of a similar product.

Eyes : Moderately irritating to eyes. *Information is based on toxicity test result of a similar product.

Sensitization

Product/ingredient name	Route of exposure	Species	Result
*LYSOL® All Purpose Cleaner - Power White & Shine Trigger with Bleach	skin	Guinea pig	Sensitizing

Conclusion/Summary

Skin : Skin sensitizer * Information is based on toxicity test result of a similar product.

Mutagenicity

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
sodium hypochlorite, solution	-	3	-

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 : Causes serious eye irritation.
Inhalation : No known significant effects or critical hazards.
Skin contact : Causes skin irritation. May cause an allergic skin reaction.
Ingestion : Irritating to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
 pain or irritation
 watering
 redness
Inhalation : No specific data.
Skin contact : Adverse symptoms may include the following:
 irritation
 redness
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

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

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.

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
sodium hypochlorite, solution	Acute EC50 46000 µg/l Marine water	Algae - Gracilaria tenuistipitata	4 days
	Acute LC50 56400 µg/l Marine water	Crustaceans - Palaemonetes pugio	48 hours
	Acute LC50 32 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 32 µg/l Marine water	Fish - Oncorhynchus kisutch - Juvenile (Fledgling, Hatchling, Weanling)	96 hours
	Chronic NOEC 10000 µg/l Marine water	Algae - Gracilaria tenuistipitata	4 days
	Chronic NOEC 0.1 ppm Fresh water	Fish - Cyprinus carpio - Young	30 days

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : Release of large quantities into water may cause a pH-change resulting in danger for aquatic life.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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12. Ecological information

Release of large quantities into water may cause a pH-change resulting in danger for aquatic life.

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. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
DOT Classification	UN3266	Corrosive liquid, basic, inorganic, n.o.s. (Sodium hypochlorite , sodium hydroxide)	8	II		<u>Limited quantity</u>
TDG Classification	UN3266	CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S. (sodium hypochlorite, solution, sodium hydroxide)	8	II		<u>Limited quantity</u>
Mexico Classification	UN3266	LIQUIDO CORROSIVO, BASICO, INORGANICO, N.E.P. (sodium hypochlorite, solution, sodium hydroxide)	8	II		<u>Limited quantity</u>
IMDG Class	UN3266	CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S. (Sodium hypochlorite , sodium hydroxide).	8	II		<u>Limited quantity</u>
IATA-DGR Class	UN3266	Corrosive liquid, basic, inorganic, n.o.s. (sodium hypochlorite, solution, sodium hydroxide)	8	II		<u>See DG List.</u>

PG* : Packing group

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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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) 311: sodium hypochlorite, solution; sodium hydroxide

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 : Reactive
 Immediate (acute) health hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
sodium hypochlorite, solution	1 - 2.5	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : The following components are listed: SODIUM HYPOCHLORITE
New York : The following components are listed: Sodium hypochlorite
New Jersey : The following components are listed: SODIUM HYPOCHLORITE; HYPOCHLOROUS ACID, SODIUM SALT
Pennsylvania : The following components are listed: HYPOCHLOROUS ACID, SODIUM SALT

Label elements

Signal word: : WARNING

Hazard statements : Causes moderate eye irritation
 Causes skin irritation.

Precautionary measures : Do not get in eyes, on skin, or on clothing.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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15. Regulatory information

Vapor may be irritating to eyes and respiratory system. Use only in a well-ventilated area. Avoid breathing vapor or spray. Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease. Harmful if swallowed. For sensitive skin, the use of gloves is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Skin sensitizer: : Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals

Additional information : Short term Skin Bleaching agent. IF ON SKIN: Rinse skin with water.

16. Other information

Hazardous Material Information System (U.S.A.) :

Health	3
Flammability	0
Physical hazards	0
Personal protection	D

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) :



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

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

Code # : FF0003419 (D0004478) **SDS #** : D0004478 v5.0 **Date of issue** : 31/03/2015.

12/13

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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16. Other information

Date of issue : 31/03/2015.
Date of previous issue : 15/06/2006.
Version : 5
Prepared by : Reckitt Benckiser LLC.
 Product Safety Department
 1 Philips Parkway
 Montvale, New Jersey 07646-1810 USA.
 FAX: 201-476-7770

Revision comments : Update as per US GHS.

☑ Indicates information that has changed from previously issued version.

Notice to reader

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.



RB is a member of the CSPA Product Care Product Stewardship Program.

SAFETY DATA SHEET

1. Identification

Product number 1000008439

Product identifier **MC CALL'S SURFACIDE COUNTRY FRESH DISINFECTANT**

Company information T. FRANK MC CALL'S INC.
601 MADISON STREET
CHESTER, PA 19013

Company phone 610-876-9245

Version # 01

Recommended use PESTICIDE

Recommended restrictions None known.

2. Hazard(s) identification

Physical hazards Flammable aerosols Category 1

Health hazards Serious eye damage/eye irritation Category 2

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Contains gas under pressure; may explode if heated. Causes serious eye irritation.

Precautionary statement

Prevention Wash thoroughly after handling. Wear eye/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.

Storage Protect from sunlight. Store in a well-ventilated place.

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	Common name and synonyms	CAS number	%
2-Butoxyethanol		111-76-2	2.5 - 10
Butane		106-97-8	1 - 2.5
EDTA Tertrasodium Salt		64-02-8	1 - 2.5
Other components below reportable levels			90 - 100

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
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	Water fog. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Contents under pressure.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	In case of fire: Stop leak if safe to do so. Do not move cargo or vehicle if cargo has been exposed to heat. Move containers from fire area if you can do so without risk. Containers should be cooled with water to prevent vapor pressure build up. For massive fire in cargo area, use unmanned hose holder or monitor nozzles, if possible. If not, withdraw and let fire burn out.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Emergency personnel need self-contained breathing equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Refer to attached safety data sheets and/or instructions for use. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil, etc.) away from spilled material. Stop leak if you can do so without risk. Move the cylinder to a safe and open area if the leak is irreparable. Isolate area until gas has dispersed. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. 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	Pressurized container: Do not pierce or burn, even after use. Do not use if spray button is missing or defective. Do not spray on a naked flame or any other incandescent material. Do not smoke while using or until sprayed surface is thoroughly dry. Do not cut, weld, solder, drill, grind, or expose containers to heat, flame, sparks, or other sources of ignition. Ground and bond containers when transferring material. Do not re-use empty containers. Do not get in eyes, on skin, or on clothing. Avoid breathing mist or vapor. Avoid prolonged exposure. Use only in well-ventilated areas. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Level 1 Aerosol. Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50°C/122 °F. Do not puncture, incinerate or crush. Do not handle or store near an open flame, heat or other sources of ignition. This material can accumulate static charge which may cause spark and become an ignition source. Refrigeration recommended. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
2-Butoxyethanol (CAS 111-76-2)	PEL	240 mg/m ³
		50 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
2-Butoxyethanol (CAS 111-76-2)	TWA	20 ppm
Butane (CAS 106-97-8)	STEL	1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
2-Butoxyethanol (CAS 111-76-2)	TWA	24 mg/m3
		5 ppm
Butane (CAS 106-97-8)	TWA	1900 mg/m3
		800 ppm

Biological limit values**ACGIH Biological Exposure Indices**

Components	Value	Determinant	Specimen	Sampling Time
2-Butoxyethanol (CAS 111-76-2)	200 mg/g	Butoxyacetic acid (BAA), with hydrolysis	Creatinine in urine	*

* - For sampling details, please see the source document.

Exposure guidelines**US - California OELs: Skin designation**

2-Butoxyethanol (CAS 111-76-2) Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

2-Butoxyethanol (CAS 111-76-2) Skin designation applies.

US - Tennessee OELs: Skin designation

2-Butoxyethanol (CAS 111-76-2) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

2-Butoxyethanol (CAS 111-76-2) Can be absorbed through the skin.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

2-Butoxyethanol (CAS 111-76-2) Can be absorbed through the skin.

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. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear appropriate chemical resistant gloves.

Skin protection

Other Wear suitable protective clothing.

Respiratory protection If permissible levels are exceeded use NIOSH mechanical filter / organic vapor cartridge or an air-supplied respirator.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using do not smoke. 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	Gas.
Form	Aerosol.
Color	Yellow.
Odor	Characteristic.
Odor threshold	Not available.
pH	11.8 - 12.8 estimated

Melting point/freezing point	Not available.
Initial boiling point and boiling range	212 °F (100 °C) estimated
Flash point	-156.0 °F (-104.4 °C) Propellant estimated
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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	60 - 70 psig @ 70F estimated
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Specific gravity	0.979 estimated estimated

10. Stability and reactivity

Reactivity	Reacts violently with strong acids. This product may react with oxidizing agents.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Do not mix with other chemicals. Contact with incompatible materials.
Incompatible materials	Acids. Strong oxidizing agents. Oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Prolonged inhalation may be harmful.
Skin contact	2-Butoxy ethanol may be absorbed through the skin in toxic amounts if contact is repeated and prolonged. These effects have not been observed in humans.
Eye contact	Causes serious eye irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Information on toxicological effects	
Acute toxicity	Harmful if swallowed, in contact with skin or if inhaled.

Product	Species	Test Results
19 OZ MC CALL'S SURFACIDE COUNTRY FRESH DISINFECTANT (CAS Mixture)		
Acute		
<i>Dermal</i>		
LD50	Rat	4536 mg/kg
<i>Inhalation</i>		
LC50	Rat	44 mg/l/4h
<i>Oral</i>		
LD50	Rat	
Components	Species	Test Results
2-Butoxyethanol (CAS 111-76-2)		
Acute		
<i>Dermal</i>		
LD50	Guinea pig	230 ml/kg, 24 Hours
		7.3 ml/kg, 4 Days
	Rabbit	450 ml/kg, 24 Hours
		435 mg/kg, 24 Hours
		0.63 ml/kg
	Rat	> 2000 mg/kg, 24 Hours
<i>Inhalation</i>		
LC50	Rabbit	400 ppm, 7 Hours
	Rat	450 ppm, 4 Hours
<i>Oral</i>		
LD100	Rabbit	695 mg/kg
LD50	Dog	> 695 mg/kg
	Guinea pig	1200 mg/kg
	Rat	530 - 2800 mg/kg
Butane (CAS 106-97-8)		
Acute		
<i>Inhalation</i>		
LC50	Mouse	1237 mg/l, 120 Minutes
		52 %, 120 Minutes
	Rat	1355 mg/l
EDTA Tertrasodium Salt (CAS 64-02-8)		
Acute		
<i>Oral</i>		
LD50	Rat	1658 mg/kg
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Irritating to skin. Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Risk of serious damage to eyes.	
Respiratory or skin sensitization		
Respiratory sensitization	Not available.	
Skin sensitization	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.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
2-Butoxyethanol (CAS 111-76-2)	3 Not classifiable as to carcinogenicity to humans.	

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Not applicable.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not likely, due to the form of the product.
Chronic effects	Prolonged inhalation may be harmful. May be harmful if absorbed through skin. 2-Butoxy ethanol may be absorbed through the skin in toxic amounts if contact is repeated and prolonged. These effects have not been observed in humans.

12. Ecological information

Ecotoxicity The product contains a substance which may cause long-term adverse effects in the environment.

Product	Species		Test Results
19 OZ MC CALL'S SURFACIDE COUNTRY FRESH DISINFECTANT (CAS Mixture)			
Aquatic			
Algae	IC50	Algae	86.0535 mg/L, 72 Hours
Crustacea	EC50	Daphnia	43604 mg/L, 48 Hours
Fish	LC50	Fish	1165 mg/L, 96 Hours
Components	Species		Test Results
2-Butoxyethanol (CAS 111-76-2)			
Aquatic			
Fish	LC50	Inland silverside (Menidia beryllina)	1250 mg/l, 96 hours
EDTA Tertrasodium Salt (CAS 64-02-8)			
Aquatic			
Algae	IC50	Algae	1.01 mg/L, 72 Hours
Fish	LC50	Bluegill (Lepomis macrochirus)	472 - 500 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Partition coefficient n-octanol / water (log Kow)	
2-Butoxyethanol	0.83
Butane	2.89
Mobility in soil	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	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contents under pressure. Do not puncture, incinerate or crush. Dispose of contents/container in accordance with local/regional/national/international regulations.
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. Do not re-use empty containers.

14. Transport information

DOT

UN number	UN1950
UN proper shipping name	Aerosols, flammable, (each not exceeding 1 L capacity)
Transport hazard class(es)	
Class	2.1
Subsidiary risk	-
Label(s)	2.1
Packing group	Not applicable.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling. Read safety instructions, SDS and emergency procedures before handling.
Special provisions	N82
Packaging exceptions	306
Packaging non bulk	None
Packaging bulk	None

This product meets the exception requirements of section 173.306 as a limited quantity and may be shipped as a limited quantity. Until 12/31/2020, the "Consumer Commodity - ORM-D" marking may still be used in place of the new limited quantity diamond mark for packages of UN 1950 Aerosols. Limited quantities require the limited quantity diamond mark on cartons after 12/31/20 and may be used now in place of the "Consumer Commodity ORM-D" marking and both may be displayed concurrently.

IATA

UN number	UN1950
UN proper shipping name	Aerosols, flammable
Transport hazard class(es)	
Class	2.1
Subsidiary risk	-
Label(s)	2.1
Packing group	Not applicable.
Environmental hazards	No.
ERG Code	10L
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling. Read safety instructions, SDS and emergency procedures before handling.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.
Packaging Exceptions	LTD QTY

IMDG

UN number	UN1950
UN proper shipping name	AEROSOLS
Transport hazard class(es)	
Class	2.1
Subsidiary risk	-
Label(s)	2.1
Packing group	Not applicable.
Environmental hazards	
Marine pollutant	No.
EmS	F-D, S-U
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling. Read safety instructions, SDS and emergency procedures before handling.
Packaging Exceptions	LTD QTY
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT



IATA; IMDG



15. Regulatory information

US federal regulations

This product is 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 - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
Anhydrous Ammonia	7664-41-7	100	500 lbs		
Hydrogen Peroxide	7722-84-1	1000	1000 lbs		

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)

Butane (CAS 106-97-8)

Safe Drinking Water Act (SDWA) Not regulated.

FIFRA Information

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 pesticide label also includes other important information, including directions for use.

US state regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

2-Butoxyethanol (CAS 111-76-2)

Butane (CAS 106-97-8)

US. New Jersey Worker and Community Right-to-Know Act

2-Butoxyethanol (CAS 111-76-2)

Butane (CAS 106-97-8)

US. Pennsylvania Worker and Community Right-to-Know Law

2-Butoxyethanol (CAS 111-76-2)

Butane (CAS 106-97-8)

US. Rhode Island RTK

Butane (CAS 106-97-8)

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)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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 06-08-2015

Version # 01

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.

Revision Information

Product and Company Identification: Alternate Trade Names



SDS DATE: 10/27/15

This safety data sheet complies with the requirements of 29CFR1910.1200.

1.0 IDENTIFICATION

PRODUCT NAME: McKesson Alcohol Prep Pads
MFR #: 58-204, 58-404, 16-527, 16-528

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 Alcohol Prep Pads

2.0 HAZARDS IDENTIFICATION

CLASSIFICATION

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Physical Hazards

Health Hazards

Environmental Hazards

OSHA defined hazards

Flammable Solids

Serious eye damage/eye irritation

Not determined

None additional

Category 1

Category 2A

Label Elements

Pictograms



Signal Word

Danger



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Hazard Statements

Flammable solid.

Causes serious eye irritation.

Precautionary Statements – Prevention

Keep away from heat/spark/open flames/hot surfaces.

No smoking.

Use only in a well ventilated area.

Precautionary Statements – Response

If case of fire: use appropriate media to extinguish.

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 control center.

If inhaled: remove victim to fresh air and keep comfortable for breathing.

Precautionary Statement – Disposal

Dispose of waste and residues in accordance with local authority requirements.

Hazards not otherwise classified (HNOC)

Not applicable

Other information

Not know.

3.0 COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms

None

Substance: Mixture

CHEMICAL NAME	CAS NO.	WEIGHT (%)
Isopropyl Alcohol	67-63-0	70
Purified Water	7732-18-5	30

4.0 FIRST AID MEASURES

DESCRIPTION OF FIRST AID MEASURES**General Advice**

Keep victim warm and quiet. Monitor for systemic secondary effects on liver and kidney. Ensure that medical personnel are aware of the material (s) involved and take precautions to protect themselves.



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Eye Contact	Immediately flush with plenty of water. After initial flushing remove any contact lenses and continue flushing for at least 15 minutes. Seek immediate medical attention/advice.
Skin Contact	In case of skin irritation, discontinue use of product. Wash off with soap and water. Get medical attention if irritation develops and persists.
Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Ingestion	If swallowed, contact a Poison Control Center immediately. Immediately rinse mouth out with water. Do not induce vomiting. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Never give anything by mouth if victim is unconscious or is convulsing.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Symptoms	May include stinging, tearing, redness, swelling and blurred vision.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Provide general supportive measures and treat asymptotically.

5.0 FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA

Use foam, dry chemical or carbon dioxide. Be aware of possibility of re-ignition. Keep containers and surroundings cool with water spray.

Unsuitable extinguishing media:	None

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

During fire, gases hazardous to health may be formed.

Explosion data	
Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None



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PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots and in enclosed spaces, SCBA. Structural firefighters protective clothing will only provide limited protection.

In case of fire or explosion, do not breathe fumes. In the event of fire, use water spray to cool fire exposed surfaces and to protect personnel. Shut off fuel to the fire. If a leak or spill has not ignited, use water spray to disperse the vapors.

6.0 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Personal Precautions	Wear appropriate protective equipment and clothing during clean up.
Other Information	Eliminate all sources of ignition.
For Emergency Responders	Use personal protective equipment as required. Vapors can accumulate in low areas. Consider need for evacuation.

ENVIRONMENTAL PRECAUTIONS

Collect spillage. Prevent material from entering water courses.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Methods for Containment	Contain and absorb using earth, sand or inert materials. Transfer into suitable containers for recovery or disposal.
Methods for Cleaning up	N/A

7.0 HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Advice on Safe Handling	Do not handle near open flame or heat sources. Do not use with electrocautery procedures. Use according to package label instructions. Discard after single use. Avoid inhaling vapor and contact with eyes.



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CONDITIONS FOR SAFE STORAGE**Storage Conditions**

Keep container closed. Store in a cool, dry, well ventilated place. Keep away from sources of ignition.

Incompatible Materials

N/A

8.0 EXPOSURE CONTROLS/PERSONAL PROTECTION

CONTROL PARAMETERS**Exposure Guidelines**

OSHA PEL Limits for Air contaminants

Isopropanol 980 mg/m³, 400 ppm

US ACGIH Threshold Limit Values

Isopropanol STEL 400 ppm

Isopropanol TWA 200 ppm

US NIOSH

Isopropanol STEL 1225 mg/m³, 500 ppm

Isopropanol TWA 980 mg/m³, 400 ppm

Biological Limit Values

ACGIH Biological Exposure Indices

Isopropanol

40mg/l, Acetone, Urine

APPROPRIATE ENGINEERING CONTROLS

Ventilation systems. Eyewash stations. Showers.

INDIVIDUAL PROTECTION MEASURES, SUCH AS PPE**Eye/Face Protection**

Wear gear deemed necessary.

Skin and Body Protection

Wear gear as deemed necessary.

Respiratory Protection

Wear positive pressure self contained breathing apparatus (SCBA)

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. When using, do not smoke. When using do not eat or drink.

9.0 PHYSICAL AND CHEMICAL PROPERTIES



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INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Liquid
Appearance	Clear, Colorless
Form	Pre-moistened towelette
Color	N/A
Odor	Alcohol odor
Odor Threshold	No information available

Property	Values	Remarks
pH (1-3% aqueous solution)	Not applicable	
Melting point/freezing point	- C	
Boiling point/boiling range	Between 82 and 83 C	
Flash point	12 C	
Evaporation rate	2.5	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air - Upper flammability limit - Lower flammability limit	LEL/UEL 2.0/12.7 vol %	Not Flammable
Vapor pressure	33 mmHg	
Vapor density	Not applicable	
Specific Gravity	0.785	
Water solubility	Not applicable	
Solubility in water	100%	
Partition coefficient	Not applicable	
Autoignition temperature	399 C	
Decomposition temperature	Not applicable	
Kinematic viscosity	Not applicable	
Dynamic viscosity	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	Not applicable	
Density	Not applicable	
Bulk Density	0.9g/cc	

10.0 STABILITY AND REACTIVITY**CHEMICAL STABILITY**

Stable under normal condition of handling, use and transport.

POSSIBILITY OF HAZARDOUS REACTIONS

None under normal processing.

Hazardous polymerization

Does not occur.



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CONDITIONS TO AVOID

Heat, flames and sparks. Avoid temperatures exceeding flash point.

INCOMPATIBLE MATERIALS

Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS

May include but are not limited to oxides of carbon.

11.0 TOXICOLOGICAL INFORMATION**INFORMATION ON LIKELY ROUTES OF EXPOSURE****Product Information**

Available toxicological data for individual ingredients are summarized below.

Inhalation

Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Health injuries are not known or expected under normal use.

Eye Contact

Causes serious eye irritation.

Skin Contact

Not expected to be a primary skin irritant.

Ingestion

Not applicable under normal conditions of use.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LD50
Isopropanol 67-63-0	5045 mg/kg (rat)	Eye 12800 mg/kg (rabbit)	16970 mg/l/4h

INFORMATION ON TOXICOLOGICAL EFFECTS

No information available.

DELAYED AND IMMEDIATE EFFECTS AS WELL AS CHRONIC EFFECTS FROM SHORT AND LONG-TERM EXPOSURE**Skin corrosion/irritation**

Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation

Causes serious irritation to the eye

Respiratory or skin sensitization

Not expected to cause skin sensitization.

Sensitization

No sensitization responses were observed.

Germ cell mutagenicity

Not expected to have chronic health effects.

Carcinogenicity

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC, ACGHI or NTP.

US OSHA Specifically Regulated Substances Not listed

Reproductivity Toxicity

Finished product not expected to have chronic health effects.

STOT- single exposure

Narcotic effects.

STOT – repeated exposure

Not classified.

Chronic Toxicity

No known effect.

Sub-chronic Toxicity

No known effect.

Neurological Effects

Not applicable.



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NUMERICAL MEASURES OF TOXICITY

Not available.

12.0 ECOLOGICAL INFORMATION**ECOTOXICITY**

Chemical Name	Algae/Aquatic Plants	Fish	Crustacea
Isopropanol 67-63-0	IC 50 100mg/L, 72 hours	LC 50 Bluegill > 1400 ml/l, 96 hours	EC 50 13299 mg/L: 72 h Daphnia magna

Persistence and degradability

No data available.

Bioaccumulation

No data available.

Partition coefficient n-octanol/water (log Kow) Isopropanol 0.05

Mobility

No data available.

Other adverse effects

None expected.

13.0 DISPOSAL CONSIDERATIONS**WASTE TREATMENT METHODS****DISPOSAL OF WASTE**

Disposal should be in accordance with applicable regional, national and local laws and regulations. Dispose of contents/containers in accordance with local regulations. This material, as supplied, is not a hazardous waste according to state and federal regulations (40 CFR 61).

Contaminated packaging

Following warning label.

State of California Hazardous Waste Status

Isopropanol (67-63-0) Listed

14.0 TRANSPORT INFORMATION**NOTE: THIS MATERIAL IS NOT SUBJECT TO REGULATION AS A DANGEROUS GOOD.****DOT**

Not regulated

TDG

Not regulated

MEX

Not regulated

ICAO

Not regulated

IATA

Not regulated

IMDG

Not regulated

RID

Not regulated

ADR

Not regulated. European requirement only.



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AND

Not regulated. European requirement only.

15.0 REGULATORY INFORMATION

INTERNATIONAL INVENTORIES

OSHA Specifically regulated substances Not listed

LEGEND

TSCA – United States Toxic Substances Control Act Section 8b Inventory

DSL/NDL – Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS – European Inventory of Existing chemical Substances/European List of Notified Chemical

ENCS – Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS – Phillipines Inventory of Chemicals and Chemical Substances

AICS – Australian Inventory of Chemical Substances

US FEDERAL REGULATION

SARA

Hazard categories	Immediate Hazard – Yes
	Delayed Hazard – No
	Fire Hazard – Yes
	Pressure Hazard – No
	Reactivity Hazard - No

SARA 302 Extremely Hazardous Substances No

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

SARA 313 (TRI Reporting)

Isopropanol (67-63-0)	40-70% by weight

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).



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FDA Regulated as a drug.

CERCLA Isopropanol (67-63-0) Listed

US STATE REGULATIONS

CALIFORNIA PROPOSITION 65

This product does not contain any Proposition 65 chemicals.

US RIGHT TO KNOW REGULATIONS

Isopropanol (67-63-0) Listed California (Hazardous Substances (Director's), Illinois, Louisiana, Minnesota, New Jersey, Massachusetts, Pennsylvania, Rhode Island

Country(s) of Origin United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory On inventory? Yes

US EPA LABEL INFORMATION

Not applicable.

16.0 OTHER INFORMATION

NFPA

Health Hazards	1
Flammability	3
Reactivity/Instability	0

HMIS

Health Hazards	1
Flammability	3
Physical Hazards	0
Personal Protection	X

Prepared by

Cypress Medical Products, LLC Quality Assurance

Disclaimer

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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 Document---



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* SAFETY DATA SHEET *

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Bacitracin ointment

MFR #: 1175

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: First Aid Antibiotic

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Topical

POTENTIAL HEALTH EFFECTS: This is a pharmaceutical material available without a prescription- use only as directed. See product packaging for further information concerning adverse effects and drug interaction precautions.

EYES: May cause irritation with symptoms of reddening, tearing and stinging

SKIN: Allergy to any ingredient may cause anaphylactic shock

INGESTION: Symptoms of ingestion may include abdominal pain, nausea, vomiting, and diarrhea.

INHALATION: N/A

ACUTE HEALTH HAZARDS: No data available for this product.

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

CARCINOGENICITY

OSHA: Not Listed ACGIH: Not Listed NTP: Not Listed IARC: Not Listed
OTHER: N/A

SECTION 2 NOTES: The components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>%</u>	<u>Exposure Limits</u>
Petrolatum	8009-03-8	10-100	N/A
Bacitracin Zinc	1405-89-6	0.1-1	LD50 (oral mouse) >3750 mg/kg LD50 (oral Guinea pig) 2gm/kg



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SECTION 3 NOTES: The formulations for these products are proprietary information. Inactive ingredients of less than 1% not displayed above.

SECTION 4: FIRST-AID MEASURES

EYES: In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.

SKIN: N/A

INGESTION: In case of accidental ingestion, contact your regional poison center or physician immediately.

INHALATION: N/A

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: Not Established
(% BY VOLUME) LOWER: Not Established

FLASH POINT: Not established

METHOD USED: N/A

AUTOIGNITION TEMPERATURE: Not Established

NFPA HAZARD CLASSIFICATION

HEALTH:	1	FLAMMABILITY:	1	REACTIVITY:	0	OTHER:	N/A

HMIS HAZARD CLASSIFICATION

HEALTH:	2	FLAMMABILITY:	1	REACTIVITY:	N/A	PERSONAL:	0

EXTINGUISHING MEDIA: Water Fog, Sand, Earth, Dry Chemical, Foam

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and sulfur oxides).

HAZARDOUS DECOMPOSITION PRODUCTS: None known

SECTION 5 NOTES: See section 9 for physical and chemical properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Scrape or shovel material. Use oil absorbent rags. Use appropriate personal protective equipment during clean up.

SECTION 6 NOTES: See Sections 9 and 10 for additional physical, chemical and hazard information.

SECTION 7: HANDLING AND STORAGE

HANDLING: Keep this and all drugs out of the reach of children. Avoid contact with eyes.

STORAGE: Store in a dry place away from excessive heat, in original or similar waterproof containers. Use normal precautions for storage of drug.

OTHER PRECAUTIONS: N/A



SDS DATE: 11/11/2015

SECTION 7 NOTES: This product is a human pharmaceutical. Follow all industry standards for use of this product.

 SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: None necessary when used as intended.

RESPIRATORY PROTECTION: None necessary when used as intended.

EYE PROTECTION: None necessary when used as intended.

SKIN PROTECTION: None necessary when used as intended.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

EXPOSURE GUIDELINES: Not established

SECTION 8 NOTES: The following guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

 SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Nearly odorless, yellow to off white

PHYSICAL STATE: ointment

pH AS SUPPLIED: Not established

pH (Other): Not established

BOILING POINT: > 200°C

MELTING POINT: Not established

FREEZING POINT: Not established

VAPOR PRESSURE (mmHg): Not established

DENSITY (lb/gal): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): 0.8

EVAPORATION RATE: Not established

BASIS (=1): N/A

SOLUBILITY IN WATER: Not soluble

PERCENT SOLIDS BY WEIGHT: Not established

PERCENT VOLATILE: Not established

BY WT/ N/A BY VOL @ N/A

VOLATILE ORGANIC COMPOUNDS (VOC): Not established

WITH WATER: N/A LBS/GAL

WITHOUT WATER: N/A LBS/GAL

MOLECULAR WEIGHT: Not established

VISCOSITY: Not established

SECTION 9 NOTES: See Section 5 for flammability/explosivity information.



SDS DATE: 11/11/2015

SECTION 10: STABILITY AND REACTIVITY

STABLEUNSTABLE

STABILITY: X

CONDITIONS TO AVOID (STABILITY): Avoid heat, light, and contact with incompatible chemicals.

INCOMPATIBILITY (MATERIAL TO AVOID): Oxidizing agents

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: None known.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: No data available for this product.

SECTION 11 NOTES: The information below pertains to the formulated product unless indicated otherwise.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: This product has not been tested for Eco toxicity.

SECTION 12 NOTES: There is no environmental data available for this product.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incarceration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

RCRA HAZARD CLASS: Not available

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 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



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SECTION 14 NOTES: This material is not subject to the transportation regulations of DOT, IATA, and the ADR.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): Exempt

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): Not Listed

SARA 311/312 HAZARD CATEGORIES: Exempt

SARA 313 REPORTABLE INGREDIENTS: Contains NO hazardous ingredients subject to reporting requirements of Section 313 of SARA Title II.

STATE REGULATIONS: The components of this product are not on the California Proposition 65 lists.

INTERNATIONAL REGULATIONS: Not applicable.

SECTION 15 NOTES: For details on your regulatory requirements you should contact the appropriate agency in your state.

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION:

SDS CREATION DATE: November 11, 2015

SDS VERSION: Original

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.



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY INFORMATION

PRODUCT NAME: McKesson Disposable Germicidal Surface Wipes

MFR #: 50-66160, 50-66170

RECOMMENDED USE: Cleaner, Disinfectant, Deodorizer

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

Classification

Hazard Class	Category
Flammable liquid	3
Eye irritation	2A
Specific target organ toxicity (single exposure)	3

Label Elements

Hazard Symbols



Signal Word(s): Warning

Hazard Statement(s): Flammable liquid and vapor. Causes serious eye irritation. May cause drowsiness or dizziness.

Precautionary Statement(s): Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/eye protection/face protection. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. 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 inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents and container in accordance with all local, regional, national and international regulations.

Other Hazards

1% of the mixture consists of ingredient(s) of unknown acute toxicity.



SECTION 3: COMPOSITION

Chemical Name	CAS Number	Wt %
Isopropyl alcohol	67-63-0	10-30
2-Butoxyethanol	111-76-2	1-5

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: Not a normal route of exposure. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER/doctor/physician if you feel unwell.

Eye Contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses, if worn. If irritation persists, get medical attention.

Ingestion: May result in obstruction and irritation if ingested. If large amounts of liquid are swallowed seek medical attention immediately.

Skin: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician if irritation develops and persists.

Most Important Symptoms and Effects (Acute and Delayed)

Inhalation: Vapors may cause drowsiness and dizziness. May cause respiratory tract irritation.

Eye Contact: Causes serious eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with marked redness and swelling of the conjunctiva.

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 & EXPLOSION HAZARD DATA

Extinguishing Media

Suitable: Water fog, carbon dioxide, dry chemical or alcohol foam.

Unsuitable: None known.

Specific Hazards Arising from Chemical

Liquid absorbed onto wipe is flammable. Product will burn if exposed to fire. Products of combustion include but are not limited to: oxides of carbon.

Protective Equipment and Precautions for Firefighters

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. Eliminate sources of ignition.

Environmental Precautions: See Section 12 for ecological information.

Methods and Material for Containment and Cleaning Up

Pick up large pieces, then place in 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 & STORAGE

Precautions for Safe Handling

Handling: Keep away from sources of ignition. No smoking. Take precautionary measures against static discharge. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not swallow. Handle and open container with care. When using do not eat, drink or smoke. Use only non-sparking tools. Use only outdoors or in well-ventilated area.

General Hygiene Advice: Launder contaminated clothing before use. Wash hands before eating, drinking, or smoking.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep locked up and out of the reach of children. Keep container tightly closed and in a well-ventilated place. Keep cool.

Incompatible Materials: Oxidizers.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Exposure Guidelines:

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl alcohol (67-63-0)	200 ppm	980 mg/m ³	Not available
2-Butoxyethanol (111-76-2)	20 ppm	240 mg/m ³	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 are recommended when using product.



General Work/Hygienic Practices: Handle in accordance with good industrial hygiene and safety practice. Do not eat, smoke or drink where material is handled, processed or stored. Wash hands carefully before eating or smoking. Handle according to established industrial hygiene and safety practices.

SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

Appearance: Wipes saturated with clear liquid

Odor: Alcohol-like

Odor threshold: Not determined

pH: 7.6 (liquid)

Melting point/freezing point: Not determined

Initial boiling point and boiling range: Not determined

Flash point: 30°C (86°F) TCC (liquid)

Evaporation rate: Not determined

Flammability (solid, gas): Flammable

Upper/lower flammability or explosive limits: Not determined

Vapor pressure: Not determined

Vapor density: Not determined

Relative density: 0.97 (liquid)

Solubility(ies): Not determined

Partition coefficient (n-octanol/water): Not determined

Auto-ignition temperature: Not determined

Decomposition temperature: Not determined

Viscosity: Not determined

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions.

Chemical stability: Stable under recommended storage conditions. May form flammable/explosive vapor-air mixture

Possibility of hazardous reactions: None under normal use.

Conditions to avoid: Heat. Incompatible materials. Sources of ignition.

Incompatible materials: Oxidizers.

Hazardous decomposition products: May include and are not limited to: oxides of carbon.



SECTION 11: TOXICOLOGICAL INFORMATION

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)	>20 mg/l/4h

Component Information:

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl alcohol (67-63-0)	4396 mg/kg (rat)	12800 mg/kg (rat)	72.6 mg/l/4h
2-Butoxyethanol (111-76-2)	470 mg/kg (rat)	Not available	450 ppm/4h

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not established

Persistence and degradability: Not established

Bioaccumulative potential: Not established

Mobility in soil: No additional information available

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. The generation of waste should be avoided or minimized whenever possible. Handle empty containers with care because residual vapors are flammable.



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.

DOT (Ground): Not regulated

IATA (Air): Not regulated

IMDG (Vessel): Not regulated

SECTION 15: REGULATORY INFORMATION

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.

CAUTION

Harmful if inhaled or absorbed through skin.

Causes moderate eye irritation.

Avoid breathing vapors, and contact with eyes, skin, or clothing.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

Remove contaminated clothing and wash clothing before reuse.

Do not use or store near heat or open flame.

All ingredients in this product are listed or are excluded from listing on the US Toxic Substances Act (TSCA) Chemical Substance Inventory.

SARA 313

This product contains chemicals which are subject to the reporting requirements of the Superfund Amendments and Reauthorization Act and Title 40 of the Code of Federal Regulations, Part 372. Chemicals: Isopropanol and Butoxyethanol.

SECTION 16: OTHER INFORMATION

Issue Date: 07-Mar-2016

Revision Date: 07-Mar-2016

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: 9/18/2015

*** SAFETY DATA SHEET *****SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: McKesson Premium Hand Sanitizer with Aloe
 MFR #: 53-27032-4, 53-27033-8, 53-27036-1000, 53-27037-18, 53-27037-18BC, 53-27038-4, 53-27039-2

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: A gelled alcohol hand sanitizer with Aloe for hand washing to decrease bacteria on the skin

2. HAZARDS IDENTIFICATION**Classification**

Flammable Liquids

Category 2

Signal Word**Danger****Hazard Statements**

Highly flammable liquid and vapor

**Appearance** Clear light green gel**Physical State** Gel**Odor** Alcohol**Precautionary Statements - Prevention**

Keep away from heat/sparks/open flames/hot surfaces. — No smoking
 Keep container tightly closed
 Ground/bond container and receiving equipment
 Use explosion-proof equipment
 Use only non-sparking tools
 Take precautionary measures against static discharge
 Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IN CASE OF FIRE: Use CO₂, dry chemical, or foam for extinction

Precautionary Statements - Storage

Store in a well-ventilated place

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Hazards

Toxic to aquatic life with long lasting effects



SDS DATE: 9/18/2015

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Ethanol	64-17-5	70

4. FIRST-AID MEASURES

First Aid Measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin Contact	If skin irritation occurs, rinse affected area with water.
Inhalation	Remove to fresh air.
Ingestion	Dilute by giving a large amount of water. Call a physician or Poison Control Center.

Most important symptoms and effects

Symptoms	Exposed individuals may experience eye tearing, redness and discomfort. May cause gastrointestinal disturbance. Inhalation may cause giddiness or loss of consciousness.

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). Alcohol resistant foam. Dry chemical.

Unsuitable Extinguishing Media Not determined.

Specific Hazards Arising from the Chemical

Vapors may travel to source of ignition and flash back. Alcohol flames may be difficult to see; the flames are virtually colorless.

Hazardous Combustion Products Carbon oxides.

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. Use cool water to cool equipment and to disperse vapors.

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	Prevent further leakage or spillage if safe to do so.



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Methods for Clean-Up

Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system.
Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling

Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Use spark-proof tools and explosion-proof equipment. Ground/bond container and receiving equipment. Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Do not contaminate food or feed stuffs. Do not reuse container. Keep out of the reach of children.

Incompatible Materials

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethanol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m ³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m ³	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m ³



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Glycerol 56-81-5	TWA: 10 mg/m ³ mist	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction (vacated) TWA: 10 mg/m ³ mist, total particulate (vacated) TWA: 5 mg/m ³ mist, respirable fraction	-
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m ³ (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m ³ (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m ³	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m ³ STEL: 500 ppm STEL: 1225 mg/m ³

Appropriate engineering controls

Engineering Controls Apply technical measures to comply with the occupational exposure limits. Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Avoid contact with eyes.

Skin and Body Protection No special technical protective measures are necessary.

Respiratory Protection No protective equipment is needed under normal use conditions.

General Hygiene Considerations Do not get in eyes. Keep away from food and drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Gel	Odor	Alcohol
Appearance	Clear light green gel	Odor Threshold	Not determined
Color	Light green		
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>	
pH	6.00-8.00		
Melting Point/Freezing Point	Not established		
Boiling Point/Boiling Range	100 °C / 212 °F		
Flash Point	21 °C / 70 °F	SETA	
Evaporation Rate	Not established		
Flammability (Solid, Gas)	Not determined		
Upper Flammability Limits	Not determined		
Lower Flammability Limit	Not determined		
Vapor Pressure	Not established		
Vapor Density	Not established		
Specific Gravity	.858 - 882		
Water Solubility	Completely soluble		
Solubility in other solvents	Not determined		
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>	
Partition Coefficient	Not determined		
Autoignition Temperature	Not determined		
Decomposition Temperature	Not determined		
Kinematic Viscosity	Not determined		
Dynamic Viscosity	6000-10000 cps		
Explosive Properties	Not determined		



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Oxidizing Properties
Density

Not determined
 7.15-7.35 lb/gal

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Avoid

Keep out of reach of children.

Incompatible Materials

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

Hazardous Decomposition Products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact

Avoid contact with eyes.

Skin Contact

Not expected to be a skin irritant during prescribed use.

Inhalation

Avoid breathing vapors or mists.

Ingestion

Do not taste or swallow.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanol 64-17-5	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
Carbomer 9003-01-4	= 2500 mg/kg (Rat)	-	-
Glycerol 56-81-5	= 12600 mg/kg (Rat)	> 21900 mg/kg (Rat)	-
Isopropyl alcohol 67-63-0	= 4396 mg/kg (Rat)	= 12800 mg/kg (Rat) = 12870 mg/kg (Rabbit)	= 72.6 mg/L (Rat) 4 h
Isopropyl Myristate 110-27-0	> 10000 mg/kg (Rat)	= 5 g/kg (Rabbit)	> 41 mg/L (Rat)
Propylene Glycol 25322-69-4	> 2 g/kg (Rat)	-	-

Information on physical, chemical and toxicological effects

Symptoms

Please see section 4 of this SDS for symptoms.



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Delayed and immediate effects as well as chronic effects from short and long-term exposure**Carcinogenicity**

Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens". IPA is classified as an IARC Group 1 chemical ONLY when manufactured by the strong-acid process. The IPA used in this product is NOT manufactured by the strong-acid process and is therefore not classifiable as a human carcinogen. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as an alcoholic beverage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethanol 64-17-5	A3	Group 1	Known	X

Legend

ACGIH (American Conference of Governmental Industrial Hygienists)

A3 - Animal Carcinogen

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 3 IARC components are "not classifiable as human carcinogens"

NTP (National Toxicology Program)

Known - Known Carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Numerical measures of toxicity

Not determined

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Toxic to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethanol 64-17-5		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through		9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static
Carbomer 9003-01-4		580: 96 h Lepomis macrochirus mg/L LC50		168: 96 h water flea mg/L EC50
Glycerol 56-81-5		51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static		500: 24 h Daphnia magna mg/L EC50
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow- through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Isopropyl Myristate 110-27-0	100: 72 h Desmodesmus subspicatus mg/L EC50	8400: 96 h Brachydanio rerio mg/L LC50 semi-static 8400: 96 h Brachydanio rerio mg/L LC50		100: 48 h Daphnia magna mg/L EC50

Persistence/Degradability

Not determined

Bioaccumulation

Not determined

Mobility

Chemical Name	Partition Coefficient



SDS DATE: 9/18/2015

Ethanol 64-17-5	-0.32

Other Adverse Effects

Not determined

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

Disposal should be in accordance with applicable regional, national and local laws and regulations.

California Hazardous Waste Status

Chemical Name	California Hazardous Waste Status
Ethanol 64-17-5	Toxic Ignitable

14. TRANSPORT INFORMATION

Note

This product as packaged in 2oz, 4oz, 8oz, 15oz & 1000mL is shipped as Limited Quantity

DOT

UN/ID No UN1170
 Proper Shipping Name Ethanol solution
 Hazard Class 3
 Packing Group II

IATA

UN/ID No UN1170
 Proper Shipping Name Ethanol solution
 Hazard Class 3
 Packing Group II

IMDG

UN/ID No UN1170
 Proper Shipping Name Ethanol solution
 Hazard Class 3
 Packing Group II

15. REGULATORY INFORMATION

International Inventories

Not determined

US Federal Regulations**SARA 313**

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Isopropyl alcohol - 67-63-0	67-63-0	0.25	1.0



SDS DATE: 9/18/2015

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals.

Chemical Name	California Proposition 65
Ethanol - 64-17-5	Carcinogen Developmental

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X
Glycerol 56-81-5	X	X	X
Isopropyl alcohol 67-63-0	X	X	X

16. OTHER INFORMATION

NFPA**Health Hazards**

Not determined

Flammability

Not determined

Instability

Not determined

Special Hazards

Not determined

HMIS**Health Hazards**

0

Flammability

3

Physical Hazards

0

Personal Protection

0

Issue Date

26-Jun-2013

Revision Date:

18-Sep-2015

Revision Note

New format

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: 9/18/2015

*** SAFETY DATA SHEET *****SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: McKesson Premium Instant Hand Sanitizer
MFR #: 53-28032-4, 53-28033-8, 53-28035-1000, 53-28037-18

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: A gelled alcohol hand sanitizer for hand washing to decrease bacteria on the skin

2. HAZARDS IDENTIFICATION**Classification**

Flammable Liquids

Category 2

Signal Word**Danger****Hazard Statements**

Highly flammable liquid and vapor

**Appearance:** Clear blue gel**Physical State** Gel**Odor** Alcohol**Precautionary Statements - Prevention**

Keep away from heat/sparks/open flames/hot surfaces. — No smoking

Keep container tightly closed

Ground/bond container and receiving equipment

Use explosion-proof equipment

Use only non-sparking tools

Take precautionary measures against static discharge

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - ResponseIN CASE OF FIRE: Use CO₂, dry chemical, or foam for extinction**Precautionary Statements - Storage**

Store in a well-ventilated place

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Hazards

Toxic to aquatic life with long lasting effects



SDS DATE: 9/18/2015

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Ethanol	64-17-5	70

4. FIRST-AID MEASURES

First Aid Measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin Contact	If skin irritation occurs, rinse affected area with water.
Inhalation	Remove to fresh air.
Ingestion	Dilute by giving a large amount of water. Call a physician or Poison Control Center.

Most important symptoms and effects

Symptoms	Exposed individuals may experience eye tearing, redness and discomfort. May cause gastrointestinal disturbance. Inhalation may cause giddiness or loss of consciousness.

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). Alcohol resistant foam. Dry chemical.

Unsuitable Extinguishing Media Not determined.

Specific Hazards Arising from the Chemical

Vapors may travel to source of ignition and flash back. Alcohol flames may be difficult to see; the flames are virtually colorless.

Hazardous Combustion Products Carbon oxides.

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. Use cool water to cool equipment and to disperse vapors.

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	Prevent further leakage or spillage if safe to do so.


SDS DATE: 9/18/2015
Methods for Clean-Up

Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system.
Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE
Precautions for safe handling
Advice on Safe Handling

Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Use spark-proof tools and explosion-proof equipment. Ground/bond container and receiving equipment. Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities
Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Do not contaminate food or feed stuffs. Do not reuse container. Keep out of the reach of children.

Incompatible Materials

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethanol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m ³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m ³	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m ³



SDS DATE: 9/18/2015

Glycerol 56-81-5	TWA: 10 mg/m ³ mist	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction (vacated) TWA: 10 mg/m ³ mist, total particulate (vacated) TWA: 5 mg/m ³ mist, respirable fraction	-
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m ³ (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m ³ (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m ³	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m ³ STEL: 500 ppm STEL: 1225 mg/m ³

Appropriate engineering controls

Engineering Controls Apply technical measures to comply with the occupational exposure limits. Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Avoid contact with eyes.

Skin and Body Protection No special technical protective measures are necessary.

Respiratory Protection No protective equipment is needed under normal use conditions.

General Hygiene Considerations Do not get in eyes. Keep away from food and drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Gel	Odor	Alcohol
Appearance	Clear blue gel	Odor Threshold	Not determined
Color	blue		
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>	
pH	6.00-8.00		
Melting Point/Freezing Point	Not established		
Boiling Point/Boiling Range	100 °C / 212 °F		
Flash Point	21 °C / 70 °F	SETA	
Evaporation Rate	Not established		
Flammability (Solid, Gas)	Not determined		
Upper Flammability Limits	Not determined		
Lower Flammability Limit	Not determined		
Vapor Pressure	Not established		
Vapor Density	Not established		
Specific Gravity	.858 - .882		
Water Solubility	Completely soluble		
Solubility in other solvents	Not determined		
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>	
Partition Coefficient	Not determined		
Autoignition Temperature	Not determined		
Decomposition Temperature	Not determined		
Kinematic Viscosity	Not determined		
Dynamic Viscosity	6000-10000 cps		
Explosive Properties	Not determined		



SDS DATE: 9/18/2015

Oxidizing Properties
Density

Not determined
7.15-7.35 lb/gal

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Avoid

Keep out of reach of children.

Incompatible Materials

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

Hazardous Decomposition Products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact

Avoid contact with eyes.

Skin Contact

Not expected to be a skin irritant during prescribed use.

Inhalation

Avoid breathing vapors or mists.

Ingestion

Do not taste or swallow.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanol 64-17-5	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
Carbomer 9003-01-4	= 2500 mg/kg (Rat)	-	-
Glycerol 56-81-5	= 12600 mg/kg (Rat)	> 21900 mg/kg (Rat)	-
Isopropyl alcohol 67-63-0	= 4396 mg/kg (Rat)	= 12800 mg/kg (Rat) = 12870 mg/kg (Rabbit)	= 72.6 mg/L (Rat) 4 h
Isopropyl Myristate 110-27-0	> 10000 mg/kg (Rat)	= 5 g/kg (Rabbit)	> 41 mg/L (Rat)
Propylene Glycol 25322-69-4	> 2 g/kg (Rat)	-	-

Information on physical, chemical and toxicological effects

Symptoms

Please see section 4 of this SDS for symptoms.



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Delayed and immediate effects as well as chronic effects from short and long-term exposure**Carcinogenicity**

Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens". IPA is classified as an IARC Group 1 chemical ONLY when manufactured by the strong-acid process. The IPA used in this product is NOT manufactured by the strong-acid process and is therefore not classifiable as a human carcinogen. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as an alcoholic beverage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethanol 64-17-5	A3	Group 1	Known	X

Legend

ACGIH (American Conference of Governmental Industrial Hygienists)

A3 - Animal Carcinogen

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 3 IARC components are "not classifiable as human carcinogens"

NTP (National Toxicology Program)

Known - Known Carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Numerical measures of toxicity

Not determined

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Toxic to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethanol 64-17-5		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through		9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static
Carbomer 9003-01-4		580: 96 h Lepomis macrochirus mg/L LC50		168: 96 h water flea mg/L EC50
Glycerol 56-81-5		51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static		500: 24 h Daphnia magna mg/L EC50
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow- through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Isopropyl Myristate 110-27-0	100: 72 h Desmodesmus subspicatus mg/L EC50	8400: 96 h Brachydanio rerio mg/L LC50 semi-static 8400: 96 h Brachydanio rerio mg/L LC50		100: 48 h Daphnia magna mg/L EC50

Persistence/Degradability

Not determined

Bioaccumulation

Not determined

Mobility

Chemical Name	Partition Coefficient



SDS DATE: 9/18/2015

Ethanol 64-17-5	-0.32

Other Adverse Effects

Not determined

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

Disposal should be in accordance with applicable regional, national and local laws and regulations.

California Hazardous Waste Status

Chemical Name	California Hazardous Waste Status
Ethanol 64-17-5	Toxic Ignitable

14. TRANSPORT INFORMATION**Note**

This product as packaged in 4oz, 8oz, 18oz & 1000mL is shipped as Limited Quantity

DOT

UN/ID No UN1170
 Proper Shipping Name Ethanol solution
 Hazard Class 3
 Packing Group II

IATA

UN/ID No UN1170
 Proper Shipping Name Ethanol solution
 Hazard Class 3
 Packing Group II

IMDG

UN/ID No UN1170
 Proper Shipping Name Ethanol solution
 Hazard Class 3
 Packing Group II

15. REGULATORY INFORMATION**International Inventories**

Not determined

US Federal Regulations**SARA 313**

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Isopropyl alcohol - 67-63-0	67-63-0	0.25	1.0



SDS DATE: 9/18/2015

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals.

Chemical Name	California Proposition 65
Ethanol - 64-17-5	Carcinogen Developmental

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X
Glycerol 56-81-5	X	X	X
Isopropyl alcohol 67-63-0	X	X	X

16. OTHER INFORMATION**NFPA****Health Hazards**

Not determined

Flammability

Not determined

Instability

Not determined

Special Hazards

Not determined

HMIS**Health Hazards**

0

Flammability

3

Physical Hazards

0

Personal Protection

0

Issue Date

23-JUN-2013

Revision Date:

18-SEP-2015

Revision Note

New format

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.



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SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: MD Science Lab® Hand Sanitizer

Manufacturer: M.D. Science Lab, LLC
2131 Blount Road
Pompano Beach, FL 33069

Telephone # for Information: (954) 725-5502

24-Hour Emergency Telephone (CHEMTREC): (800) 424-9300

Recommended Use of Chemical and Restrictions on Use

Recommended Use: Hand Sanitizer

Restrictions on Use: This is a personal care product that is safe for consumers and other users under normal and reasonably foreseeable use. 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: HAZARD(S) IDENTIFICATION

"Consumer Products", as defined by the US Consumer Product Safety Act and which are used as intended (typical consumer duration and frequency), are exempt from the OSHA Hazard Communication Standard (29 CFR 1910.1200). This SDS is being provided as courtesy to help assist in the safe handling and proper use of the product.

GHS CLASSIFICATION: Flammable Liquids Category 3
Eye irritation Category 2A



PICTOGRAM:

SIGNAL WORD:

HAZARD STATEMENT:

LABEL ELEMENTS:

WARNING

FLAMMABLE LIQUID AND VAPOR

	<u>NPCA - HMIS</u>	<u>NFPA 704</u>	<u>KEY</u>
HEALTH	2	2	4 – Severe
FLAMMABILITY	3	3	3 – Serious
REACTIVITY	0	0	2 – Moderate
			1 – Slight
			0 – Minimal



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SAFETY DATA SHEET

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Composition of the product is a trade secret in accordance with paragraph (i) of §1910.1200 of the 29 CFR 1910 - Occupational Safety and Health Standards – Subpart Z – Toxic and Hazardous Substances.

Component	CAS #	%
Ethyl Alcohol	64-17-5	50-100
Water	7732-18-5	10-50
AMP-Acrylates/ Vinyl Isodecanoate Crosspolymer	N/A	0-10
Glycerin	56-81-5	0-10
Aloe Barbadensis Leaf Juice	8001-97-6	0-10
Tocopheryl Acetate	7695-91-2	0-10
Melaleuca Alternifolia (Tea Tree) Leaf Oil	68647-73-4	0-10

SECTION 4: FIRST AID MEASURES

EYE CONTACT:	Flush the eyes with large amounts of water until irritation subsides. If irritation persists, get medical attention.
SKIN CONTACT:	Flush with large amounts of water, use soap if available. Remove grossly contaminated clothing, including shoes. And launder before reuse.
INHALATION:	Using proper respiratory protection, immediately remove affected victim from exposure. Administer artificial respiration if breathing has stopped. Keep at rest. Call for prompt medical attention.
INGESTION:	if swallowed, DO NOT induce vomiting. Keep at rest, get prompt medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

FIRE FIGHTING:	Use water spray to cool fire exposed surfaces and to protect personal. Isolate "fuel" supply from fire. Use foam, dry chemical, or carbon dioxide to extinguish fire. Avoid spraying water directly into storage containers due to danger of boil over.
CONDITIONS TO AVOID:	Heat, sparks, flame.
HAZARDOUS DECOMPOSITIONS PRODUCTS:	Carbon monoxide, carbon dioxide, and other oxides may be generated as products of combustion.
HAZARDOUS POLYMERIZATION:	Will not occur.
SENSITIVITY TO STATIC DISCHARGE:	Yes

SECTION 6: ACCIDENTAL RELEASE MEASURES



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SAFETY DATA SHEET

SPILL: Smalls spills may be flushed to drain with large quantities of water. Large spills should be diked and contained, then absorbed with non-reactive materials and placed in disposable containers. A vapor suppressing foam may be used to reduce vapors. Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

SECTION 7: HANDLING AND STORAGE

ELECTROSTATIC ACCUMULATION HAZARD:	Use proper grounding procedure
STORAGE TEMPERATURE	Ambient
STORAGE/TRANSPORT PRESSURE	Atmospheric
LOADING/UNLOADING TEMPERATURE	Ambient
VISCOSITY AT LOADING/UNLOADING TEMP.	No Viscosity

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limit:	None Established.
Ventilation:	No Required
Respiratory Protection:	No Required.
Skin Protection:	No Required
Eye Protection:	No Required.
Other Protective Measures:	An eye wash facility should be available in the area.

SECTION 9: PHYSICAL & CHEMICAL PROPERTIES

Appearance:	Clear Colorless Liquid
Odor:	Alcohol like
Odor Threshold:	No Data Available
pH:	6.5 – 8.5
Boiling Point:	212°F
Flash Point:	73 °F
Solubility in water:	Miscible with water
Specific Gravity:	0.88
Viscosity of Liquid:	No Viscosity
% Solids:	No Data Available
Stability:	Stable



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SAFETY DATA SHEET

SECTION 10: REACTIVITY DATA

CONDITIONS TO AVOID HAZARDOUS POLYMERIZATION:	Not Applicable
CHEMICAL STABILITY:	Stable under recommended storage conditions
CONDITIONS TO AVOID:	Heat, flames and sparks
HAZARDOUS DECOMPOSITION PRODUCTS:	Carbon oxides

SECTION 11: TOXICOLOGICAL INFORMATION

This product is a "MIXTURE" for which no health hazard data exist. The hazard communication standard requires that such mixtures be assumed to present the same health hazards as do components that constitute at least 1% of the mixture (0.1% for Carcinogens) although OSHA has noted the hazards of individual components may be altered by including them in a mixture. One or more of the components present in greater than 1% concentration may present the following health effects, based on the evaluation of the individual components.

EYE CONTACT:	This product is irritating to the eyes upon direct contact.
SKIN CONTACT:	This product is not expected to irritate the skin under conditions of normal use.
INHALATION:	May cause irritation of respiratory tract..
INGESTION:	Although an unlikely route of entry, ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

SECTION 12: ECOLOGICAL INFORMATION

N/A

SECTION 13: DISPOSAL CONSIDERATIONS

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. Care should be taken when handling emptied containers that have been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: TRANSPORT INFORMATION

This product is not known to be hazardous but, as with all chemicals handle with care.

SECTION 15: REGULATORY INFORMATION

CERCLA:



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SAFETY DATA SHEET

If this product is accidentally spilled, it is not subject to any special reporting under the requirements of the Comprehensive response, Compensation, and Liability Act (CERCLA). We recommend you obtain local reporting requirements.

SARA TITLE III:

Under the provisions of Title III, Sections 311/312 of the Superfund Amendments and reauthorization Act, this product is classified into the following hazard categories: Delayed Health, Fire.

SECTION 16:	OTHER INFORMATION

Data Prepared: April, 2020

This safety data sheet is offered solely for your information, consideration and investigation. The data described in this SDS consist of data on literature, our acquisitional data and analogical inference by data of similar chemical substance or product. M.D. Science Lab, LLC provides no warranties, either expressed or implied, and assumes no responsibility for the accuracy or completeness of the data contained herein.



SAFETY DATA SHEET

Revision date: 13-Sep-2016

Version: 1.0

Page 1 of 10

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Methotrexate Injection, USP (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
 275 North Field Drive
 Lake Forest, Illinois 60045
 1-800-879-3477

Hospira UK Limited
 Horizon
 Honey Lane
 Hurley
 Maidenhead, SL6 6RJ
 United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2
 Reproductive Toxicity: Category 1A

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
 H341 - Suspected of causing genetic defects

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood
 P281 - Use personal protective equipment as required
 P308 + P313 - IF exposed or concerned: Get medical attention/advice
 P405 - Store locked up
 P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Material Name: Methotrexate Injection, USP (Hospira, Inc.)
 Revision date: 13-Sep-2016

Page 2 of 10
 Version: 1.0

**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methotrexate	59-05-2	200-413-8	Acute Tox.3 (H301) Repr.1A (H360D) Muta.2 (H341)	2.5
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**
Hydrochloric Acid	7647-01-0	231-595-7	STOT SE 3 (H335) Skin Corr. 1A (H314) Press. Gas Acute Tox. 3 (H331)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Additional Information:

* Proprietary
 ** to adjust pH
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
 In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES**Description of First Aid Measures****Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product Antineoplastic

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Methotrexate

Pfizer OEL TWA-8 Hr: 2 µg/m³

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm
	8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m ³
Germany (DFG) - MAK	2 ppm
	3.0 mg/m ³
Greece OEL - TWA	5 ppm
	7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm
	8 mg/m ³
Italy OEL - TWA	5 ppm
	8 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear Yellow
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Water for Injection

No data available

Sodium chloride

No data available

Hydrochloric Acid

No data available

Sodium hydroxide

No data available

Methotrexate

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May be absorbed through the skin and cause systemic effects.

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11. TOXICOLOGICAL INFORMATION

Long Term: The use of this drug during pregnancy has resulted in birth defects. Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Effects on blood and blood-forming organs have also occurred.

Acute Toxicity: (Species, Route, End Point, Dose)**Sodium chloride**

Rat Oral LD50 3000 mg/kg
 Mouse Oral LD50 4000 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Methotrexate

Rat Oral LD50 135 mg/kg
 Rat Sub-tenon injection (eye) LD50 6mg/kg
 Rat Intravenous LD50 14mg/kg
 Mouse Oral LD50 146mg/kg
 Not Specified Inhalation LC50 > 188ug/m³

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)**Sodium chloride**

Eye Irritation Rabbit Moderate
 Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
 Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Methotrexate**

4 Week(s) Rat Oral 5.6 mg/kg LOAEL Bone marrow, Liver
 6 Week(s) Rat Oral 4.2 mg/kg LOAEL Bone Marrow, Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**Methotrexate**

Embryo / Fetal Development Mouse Oral 10 mg/kg/day NOAEL Not teratogenic
 Embryo / Fetal Development Mouse Oral 25-50 mg/kg/day LOAEL Teratogenic
 Embryo / Fetal Development Monkey Intravenous 30 mg/kg/day LOAEL Developmental toxicity
 Embryo / Fetal Development Rat Intraperitoneal 5 mg/kg LOAEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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11. TOXICOLOGICAL INFORMATION**Methotrexate**

In Vitro Chromosome Aberration Human Lymphocytes Positive
In Vitro Sister Chromatid Exchange Mouse Positive
Unscheduled DNA Synthesis Human Lymphocytes Positive
In Vivo Micronucleus Mouse Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

Methotrexate
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Methotrexate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity 1/1/1989
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-413-8

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6
	215-185-5

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed

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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

16. OTHER INFORMATION**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Revision date: 13-Sep-2016

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION	
<i>Product Information</i>	
Product name	ORENCIA® (abatacept) Subcutaneous Injection, 125 mg/ml
Version	2.0, 04/22/2016
Jurisdiction	This Safety Data Sheet was prepared for the Globally Harmonized System (GHS).
Synonyms	Abatacept Injection, Subcutaneous; CTLA-4 Ig Injection, Subcutaneous; CTLA-4 Immunoglobulin Injection, Subcutaneous; BMS-188667-01 Injection, Subcutaneous; BMS 188667-01 Injection, Subcutaneous
Intended Uses	This material is a finished drug product for patient use. It is used to treat autoimmune disorders. It is a protein.
<i>Company/Undertaking Identification</i>	
Address	Bristol-Myers Squibb Australia Pty Ltd 4 Nexus Court, Mulgrave, Victoria 3170, Australia
Emergency Phone Number	CHEMTREC Australia (Sydney): +(61)-290372994

2. HAZARDS IDENTIFICATION	
UN Globally Harmonized System (GHS)	
Classification	Carcinogenicity - Category 2 Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1
Symbol	
Signal Word	Danger
Hazard Statements	Suspected of causing cancer. Causes damage to organs (immune system, teeth) through prolonged or repeated exposure.
Precautionary Statements	Do not breathe gas/fumes/vapour/spray/mist Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

Continued

ORENCIA® (abatacept)
Subcutaneous Injection, 125 mg/ml

Bristol-Myers Squibb Australia Pty Ltd
 000000122237

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2. HAZARDS IDENTIFICATION

Other information 0.03% of the mixture consists of ingredient(s) of unknown acute toxicity.
 29.5% of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS-No.
<i>Hazardous components</i>		
Abatacept	12.5 %	332348-12-6
Sucrose	<20 %	57-50-1
<i>Other ingredients</i>		
Non-Hazardous Ingredients	<75 %	Not available

4. FIRST AID MEASURES

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
Notes to Physician	This product has been reported to interact with the following medications: live viruses vaccine, TNF blocking agents. Refer to Section 11.
Medical Surveillance	The need for a pre-placement physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: a complete blood count with differential, a blood test for liver function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. It is recommended that the content be similar to the pre-placement exam. Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Material is an aqueous solution. Not expected to be flammable.
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.

Continued

5. FIRE-FIGHTING MEASURES

Protection of Firefighters	Specific hazards: Not available Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), nitrogen oxides (NOx), and, oxides of phosphorus
Other information:	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE

Handling Precautions	Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage Conditions	Keep refrigerated. (2 - 8 °C) Protect against light. Keep away from heat, sparks and flames. Store locked up.
Container Requirements	Store in the original primary packaging as provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Abatacept	85 µg/m3 TWA	--	--	--
Sucrose	--	10 mg/m3 TWA	--	10 mg/m3 TWA 5 mg/m3 TWA
Exposure Control Band	Not available			
Bristol-Myers Squibb Exposure Guidelines Summary	Not available			

Continued

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at (USA) 732-227-6338. General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.
EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED	
This formulation contains an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the API below the recommended guideline, the material as supplied should be controlled during handling to limit total airborne aerosol exposure to: 680 µg/m³.	
Engineering Controls and Ventilation	FOR MANUFACTURING PROCESSES (BULK): If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 150 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities from 150 milligrams to 1 kilogram, work in a standard laboratory using a fume hood; biological safety cabinet(Class II, all types), approved vented enclosure; specific local exhaust. Quantities exceeding 1 kilogram should be handled in a designated laboratory. A laminar flow/powder containment booth is recommended for handling >1 kilograms of active substance. When handling solutions with low energy operations (pipette transfers, pouring, low velocity stirring, fraction collection, etc.) use protective shielding to limit the spread of splash or splatter. FOR CLINICAL SETTING USE (DRUG PRODUCT): When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed. If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.
Respiratory protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.
Eye protection	Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	Wear a laboratory coat when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat (EN 340) or coverall of low permeability.
Hygiene	Wash hands and face before breaks and immediately after handling the product.

Continued

9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance

Physical State	liquid
Color	Clear, colorless to pale yellow solution
Form	aqueous solution

Other information

Molecular Weight	Not applicable
Molecular formula	Not applicable
Bulk density	Not available
Evaporation rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coefficient [log Kow]	
Surface Tension	Not available
Odor	Not available
Odor Threshold	Not available
pH	6.8 - 7.4
pKa	Not available
Particle Size	Not available
Solubility, Water	Not available
Specific Gravity/ Relative density	Not available
Viscosity	Not available

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available

Explosive limits, UEL

Explosiveness	Not available
Flammability	Nonflammable
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available

Vapor Properties

Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY
Stability

Chemical Stability	Stable under normal conditions.
Conditions to avoid	Not available
Incompatible products	Not available

Continued

10. STABILITY AND REACTIVITY

Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), nitrogen oxides (NOx), and, oxides of phosphorus
Hazardous reactions	None known.

11. TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, inhalation, Eye contact, Skin contact
Eye Irritation	<u>Sucrose</u> Dust may cause mechanical irritation.
Skin Irritation	<u>Sucrose</u> Dust may cause mechanical irritation.
Respiratory Irritation	<u>Sucrose</u> Dust may cause mechanical irritation.
Sensitization	Not available
Acute Toxicity Study	Acute Oral <u>Sucrose</u> LD50 (rat): 29,700 mg/kg Acute toxicity (other routes of administration) <u>Abatacept</u> LD50 (monkey, intravenous): 125 mg/kg No mortality occurred. LD50 (mouse, intravenous): > 100 mg/kg No mortality occurred. LD50 (rat, subcutaneous): > 100 mg/kg No mortality occurred. <u>Sucrose</u> LD50 (mouse, intraperitoneal): 14,000 mg/kg
Repeated Dose Toxicity	<u>Abatacept</u> 5 D - 12 months parenteral (1/week - daily) mouse, rat, mouse, monkey study with recovery period (3 - 4 months): LOAEL = 7 mg/kg (males and females). Low dose effects include (<= 100 mg/kg): hypoactivity, decreased food consumption, lymphoid depletion, decreased immunoglobulins, decreased white blood cell count, changes in clinical chemistry parameters, immunogenic responses, measurable drug-specific antibodies, damage at injection sites, increased organ weights included:, spleen, decreased organ weights included:, thymus, lymph nodes. Low dose microscopic effects include: lymph nodes, spleen. High dose microscopic effects include: kidney. After recovery, most parameters returned to normal. Effects still present after recovery. measurable drug-specific antibodies
Genetic Toxicity	<u>Abatacept</u> In vitro Ames reverse-mutation assay -- negative

Continued

11. TOXICOLOGICAL INFORMATION

Forward gene mutation assay -- negative
Chromosome aberration test in vitro -- negative
Sucrose
Mutagenicity Assessment
Not classified as mutagen according to GHS criteria.

Carcinogenicity Abatacept
88 Weeks subcutaneous (1/week) mouse study : Tumor LOAEL = [tumor organs:
lymphatic system, mammary gland] The reported tumors are considered to be due to a
secondary response to chronic immunosuppression.
Carcinogenicity Assessment
This material has limited evidence of carcinogenic potential. See "Human Experience".

Sucrose
Carcinogenicity Assessment
Not classifiable as to its carcinogenicity to humans.

Carcinogenicity	ACGIH	OSHA	NTP	IARC
Abatacept	--	--	--	--
Sucrose	A4	--	--	--

Reproductive Toxicity Abatacept
intravenous (every 3 days) Study of Fertility and Early Embryonic Development (rat)
NOAEL = 200 mg/kg
No effects were found on mating or fertility. No effects were observed in the
fetus/embryo.
intravenous (every 3 days) Study of Pre- and Postnatal Development (rat)
(females) LOAEL = 200 mg/kg
Fetal effects include: immunogenic responses.

Sucrose
4 Days oral (daily) Reproductive and developmental study (rat)
No effects were observed

Continued

11. TOXICOLOGICAL INFORMATION

Developmental Toxicity

Abatacept

9 Days intravenous (daily) Study of Embryo-Fetal Development (mouse)

NOAEL = 300 mg/kg

No significant adverse effects were observed.

9 Days intravenous (daily) Study of Embryo-Fetal Development (rat)

NOAEL = 200 mg/kg

No significant adverse effects were observed.

9 days intravenous (daily) Study of Embryo-Fetal Development (rabbit)

NOAEL = 200 mg/kg

No significant adverse effects were observed.

2 weeks intravenous (every 3 days) Study of Pre- and Postnatal Development (rat)

(F1 offspring) NOAEL = 45 mg/kg

Offspring effects include: immunogenic responses.

3 months - 13 weeks parenteral (every 3 days) Developmental immunotoxicity study (rat)

(juveniles, males and females) LOAEL = 20 mg/kg

Offspring effects include: changes in immunological parameters, infection, death, increased organ weights included; thymus, Microscopic changes were observed in the following organs: lymph nodes, spleen, thyroid gland, pancreas, prostate, seminal vesicles, Effects considered species specific and may not be relevant for humans include: autoimmune symptoms.

Developmental Toxicity Assessment

Available data do not indicate a potential for selective developmental toxicity. This material has been shown to cross the placenta. This compound and/or its metabolites may be excreted into the milk.

Sucrose

Developmental Toxicity Assessment

Fetal malformations were observed after very high doses in animal studies.

Human experience

Experiences with Human Exposure

Abatacept

Clinical trial(s) Intravenous and subcutaneous route low exposure - acute effects

include: headache, dizziness, numbness, fatigue, blurred vision, nausea, vertigo, diarrhoea, abdominal pain, joint pain, muscle pain, rash, changes in blood pressure, skin sensation changes, infusion reaction, hypersensitivity. low exposure - long term exposure effects include: infection, hypertension, cardiac disorders, vascular disorders, blood disorders, psychiatric disorders, eye disorders, respiratory disorders, gastrointestinal tract disorders, skin disorders, alopecia, increased liver enzymes, malignancies.

Sucrose

General effects low exposure - acute effects include: cavities. low exposure - long term exposure effects include: skin disorders.

ORENCIA® (abatacept)
Subcutaneous Injection, 125 mg/ml

Bristol-Myers Squibb Australia Pty Ltd
000000122237

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11. TOXICOLOGICAL INFORMATION

Target Organs	<u>Abatacept</u> immune system <u>Sucrose</u> teeth
Symptoms	<u>Abatacept</u> See "Human Experience". <u>Sucrose</u> See "Human Experience".
Pharmacokinetics/ Toxicokinetics	<u>Abatacept</u> Absorption: Data available upon request. Distribution: Data available upon request. Metabolism: Data available upon request. Elimination: Half-life = 16.7 Hour(s) (Human). healthy volunteers
Other Toxicity Information	Other Toxicity Tests <u>Abatacept</u> In vivo safety pharmacology test(s) : no drug related effects

12. ECOLOGICAL INFORMATION

Ecotoxicological Information (Aquatic)	Not available
Ecotoxicological Information (Terrestrial)	Not available
Chemical fate information	Not available

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	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. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation in all modes.

15. OTHER REGULATORY INFORMATION

United States of America	
OSHA Hazard Classification	
313 Toxic Release Inventory	No components listed on the SARA 313 inventory.

Continued

ORENCIA® (abatacept)
Subcutaneous Injection, 125 mg/ml

Bristol-Myers Squibb Australia Pty Ltd
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15. OTHER REGULATORY INFORMATION

TSCA Inventory Not listed. Food, drug and cosmetic products are exempt from TSCA.

Europe

DRUG PRODUCT

Classification Medicinal products are exempt from classification and labeling requirements under EU Regulation (EC) No 1272/2008.

16. OTHER INFORMATION

SDS preparation information

Prepared by Research and Development Environment, Health and Safety 1-732-227-7380

Prepared on 09/09/2015

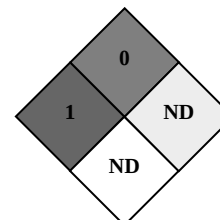
This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 2, 3, 11, 15, and 16.

Other information

HMIS	Health	1*
	Flammability	0
	Reactivity	Not Determined (ND)
	Personal protective equipment	See Section 8.

NFPA

Health 1
 Fire 0
 Reactivity ND
 Special ND



The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.

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2.2 : Non-flammable, non-toxic gases 5.1 : Oxidizing substances

Danger



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

1.1. Product identifier

Trade name : Oxygen ; Oxygen Lazer P; Medical Oxygen; Mapcon Oxygen
SDS Nr : YPX097A . (Replaces EIGA097A, 23.02.2010.)
Chemical description : Oxygen
CAS No : 7782-44-7
EC No : 231-956-9
Index No : 008-001-00-8
Registration-No. : Listed in Annex IV / V REACH, exempted from registration.
Chemical formula : O₂

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

Relevant identified uses : Industrial and professional. Perform risk assessment prior to use.
Test gas/Calibration gas. Laboratory use.
Shield gas for welding processes. Laser gas.
Plasma gas. Combustion processes. Food applications. Medical applications.
Water treatment.
Use for manufacture of electronic/photovoltaic components.
Contact supplier for more information on uses.

1.3. Details of the supplier of the safety data sheet

Company identification : Yara Praxair AS
Postboks 23 Haugenstua,
N-0915 Oslo, NORWAY
Tel. +47 04277
E-mail: norge@yarapraxair.com

1.4. Emergency telephone number

Emergency telephone number : 22 59 13 00 [24 t - Giftinformasjonssentralen]
48 00 50 00 [24 t - Beredskapstelefon Yara Praxair]

Yara Praxair AS

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E-mail: norge@yarapraxair.com

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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

Hazard Class and Category Code Regulation EC 1272/2008 (CLP)

- Physical hazards : Oxidizing gases - Category 1 - Danger - (CLP : Ox. Gas 1) - H270
Gases under pressure - Compressed gas - Warning - (CLP : Press. Gas) - H280

Classification EC 67/548 or EC 1999/45

: O; R8

2.2. Label elements

Labelling Regulation EC 1272/2008 (CLP)

- Hazard pictograms



- Hazard pictograms code : GHS03 - GHS04
- Signal word : Danger
- Hazard statements : H270 - May cause or intensify fire; oxidiser.
H280 - Contains gas under pressure; may explode if heated.
- Precautionary statements
 - Prevention : P244 - Keep valves and fittings free from oil and grease
P220 - Keep away from combustible materials.
 - Response : P370+P376 - In case of fire : Stop leak if safe to do so.
 - Storage : P403 - Store in a well-ventilated place.

2.3. Other hazards

: None.

SECTION 3. Composition/information on ingredients

3.1. Substance / 3.2. Mixture

Substance.

Substance name	Contents	CAS No EC No Index No Registration no	Classification(DSD)	Classification(CLP)
Oxygen	: 100 %	7782-44-7 231-956-9 008-001-00-8 * 1	O; R8	Ox. Gas 1 (H270) Press. Gas Compressed (H280)

Contains no other components or impurities which will influence the classification of the product.

* 1: Listed in Annex IV / V REACH, exempted from registration.

* 2: Registration deadline not expired.

* 3: Registration not required: Substance manufactured or imported < 1t/y.

Full text of R-phrases see section 16. Full text of H-statements see section 16.

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SECTION 4. First aid measures

4.1. Description of first aid measures

- Inhalation : Remove victim to uncontaminated area.
- Skin contact : Adverse effects not expected from this product.
- Eye contact : Adverse effects not expected from this product.
- Ingestion : Ingestion is not considered a potential route of exposure.

4.2. Most important symptoms and effects, both acute and delayed

- : Continuous inhalation of concentrations higher than 75% may cause nausea, dizziness, respiratory difficulty and convulsion.

4.3. Indication of any immediate medical attention and special treatment needed

- : None.

SECTION 5. Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray or fog.
- Unsuitable extinguishing media : Do not use water jet to extinguish.

5.2. Special hazards arising from the substance or mixture

- Specific hazards : Exposure to fire may cause containers to rupture/explode. Supports combustion.
- Hazardous combustion products : None.

5.3. Advice for fire-fighters

- Specific methods : Use fire control measures appropriate for the surrounding fire. Exposure to fire and heat radiation may cause gas receptacles to rupture. Cool endangered receptacles with water spray jet from a protected position. Prevent water used in emergency cases from entering sewers and drainage systems. If possible, stop flow of product. Use water spray or fog to knock down fire fumes if possible.
- Special protective equipment for fire fighters : Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters. Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask. Standard EN 469 - Protective clothing for firefighters. Standard - EN 659: Protective gloves for firefighters.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- : Try to stop release. Ensure adequate air ventilation. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. Monitor concentration of released product. Eliminate ignition sources. Evacuate area.

6.2. Environmental precautions

- : Try to stop release.

6.3. Methods and material for containment and cleaning up

- : Ventilate area.

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SECTION 6. Accidental release measures (continued)

6.4. Reference to other sections

: See also sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Safe use of the product

: Only experienced and properly instructed persons should handle gases under pressure. The substance must be handled in accordance with good industrial hygiene and safety procedures.
 Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.
 Use no oil or grease.
 Do not smoke while handling product.
 Keep equipment free from oil and grease.
 Use only oxygen approved lubricants and oxygen approved sealings.
 Use only with equipment cleaned for oxygen service and rated for cylinder pressure.
 Ensure the complete gas system was (or is regularly) checked for leaks before use.
 Consider pressure relief device(s) in gas installations.

Safe handling of the gas receptacle

: Refer to supplier's container handling instructions.
 Suck back of water into the container must be prevented.
 Open valve slowly to avoid pressure shock.
 Do not allow backfeed into the container.
 Protect cylinders from physical damage; do not drag, roll, slide or drop.
 When moving cylinders, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport cylinders.
 Leave valve protection caps in place until the container has been secured against either a wall or bench or placed in a container stand and is ready for use.
 If user experiences any difficulty operating cylinder valve discontinue use and contact supplier.
 Never attempt to repair or modify container valves or safety relief devices.
 Damaged valves should be reported immediately to the supplier.
 Keep container valve outlets clean and free from contaminants particularly oil and water.
 Replace valve outlet caps or plugs and container caps where supplied as soon as container is disconnected from equipment.
 Close container valve after each use and when empty, even if still connected to equipment.
 Never attempt to transfer gases from one cylinder/container to another.
 Never use direct flame or electrical heating devices to raise the pressure of a container.
 Do not remove or deface labels provided by the supplier for the identification of the cylinder contents.

7.2. Conditions for safe storage, including any incompatibilities

: Keep container below 50°C in a well ventilated place.
 Segregate from flammable gases and other flammable materials in store. Containers should be stored in the vertical position and properly secured to prevent toppling. Stored containers should be periodically checked for general condition and leakage. Container valve guards or caps should be in place. Store containers in location free from fire risk and away from sources of heat and ignition.
 Containers should not be stored in conditions likely to encourage corrosion. Keep away from combustible materials.

7.3. Specific end use(s)

: None.

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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

DNEL: Derived no effect level (Workers)

: No data available.

PNEC: Predicted no effect concentration

: No data available.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

: Systems under pressure should be regularly checked for leakages.
Avoid oxygen rich (>23,5%) atmospheres.
Gas detectors should be used when oxidising gases may be released.
Provide adequate general and local exhaust ventilation.
Consider work permit system e.g. for maintenance activities.

8.2.2. Individual protection measures, e.g. personal protective equipment

: PPE compliant to the recommended EN/ISO standards should be selected.
A risk assessment should be conducted and documented in each work area to assess the risks related to the use of the product and to select the PPE that matches the relevant risk.
The following recommendations should be considered:
Wear suitable hand, body and head protection. Wear goggles with suitable filter lenses when use is cutting/welding.

• Eye/face protection

: Wear safety glasses with side shields.
Standard EN 166 - Personal eye-protection.

• Skin protection

- Hand protection

: Wear working gloves when handling gas containers.
Standard EN 388 - Protective gloves against mechanical risk.

- Other

: Wear safety shoes while handling containers.
Standard EN ISO 20345 - Personal protective equipment - Safety footwear.
Standard EN ISO 14116 - Limited flame spread materials.
Consider the use of flame resistant safety clothing.

• Respiratory protection

: None necessary.

• Thermal hazards

: None necessary.

8.2.3. Environmental exposure controls

: None necessary.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state at 20°C / 101.3kPa

: Gas.

Colour

: Colourless.

Odour

: No odour warning properties.

Odour threshold

: Odour threshold is subjective and inadequate to warn for overexposure.

pH value

: Not applicable.

Molar mass [g/mol]

: 32

Melting point [°C]

: -219

Boiling point [°C]

: -183

Critical temperature [°C]

: -118

Flash point [°C]

: Not applicable for gases and gas-mixtures.

Evaporation rate (ether=1)

: Not applicable for gases and gas-mixtures.

Flammability range [vol% in air]

: Non flammable.

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SECTION 9. Physical and chemical properties (continued)

Vapour pressure [20°C]	: Not applicable.
Relative density, gas (air=1)	: 1.1
Relative density, liquid (water=1)	: 1.1
Solubility in water [mg/l]	: 39
Partition coefficient n-octanol/water [log Kow]	: Not applicable for inorganic gases.
Auto-ignition temperature [°C]	: Not applicable.
Viscosity at 20°C [mPa.s]	: Not applicable.
Explosive Properties	: Not applicable.
Oxidising Properties	: Oxidiser.
- Coefficient of oxygen equivalency (Ci)	: 1

9.2. Other information

Other data	: Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.

SECTION 10. Stability and reactivity

10.1. Reactivity

: No reactivity hazard other than the effects described in sub-sections below.

10.2. Chemical stability

: Stable under normal conditions.

10.3. Possibility of hazardous reactions

: Violently oxidises organic material.

10.4. Conditions to avoid

: None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

: Consider the potential toxicity hazard due to the presence of chlorinated or fluorinated polymers in high pressure (> 30 bar) oxygen lines in case of combustion.
May react violently with combustible materials.
May react violently with reducing agents.
Keep equipment free from oil and grease.
For additional information on compatibility refer to ISO 11114.

10.6. Hazardous decomposition products

: None.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: No known toxicological effects from this product.
Skin corrosion/irritation	: No known effects from this product.
Serious eye damage/irritation	: No known effects from this product.
Respiratory or skin sensitisation	: No known effects from this product.
Carcinogenicity	: No known effects from this product.
Germ cell mutagenicity	: No known effects from this product.

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SECTION 11. Toxicological information (continued)

Reproductive toxicity	: No known effects from this product.
STOT-single exposure	: No known effects from this product.
STOT-repeated exposure	: No known effects from this product.
Aspiration hazard	: Not applicable for gases and gas-mixtures.

SECTION 12. Ecological information

12.1. Toxicity

: No ecological damage caused by this product.

12.2. Persistence and degradability

: No ecological damage caused by this product.

12.3. Bioaccumulative potential

: No ecological damage caused by this product.

12.4. Mobility in soil

: No ecological damage caused by this product.

12.5. Results of PBT and vPvB assessment

: Not classified as PBT or vPvB.

12.6. Other adverse effects

Effect on ozone layer	: None.
Effect on the global warming	: No known effects from this product.

SECTION 13. Disposal considerations

13.1. Waste treatment methods

: May be vented to atmosphere in a well ventilated place.
Do not discharge into any place where its accumulation could be dangerous.
Refer to the EIGA code of practice Doc.30 "Disposal of Gases", downloadable at <http://www.eiga.org> for more guidance on suitable disposal methods.

List of hazardous waste codes (from Commision Decision 2001/118/EC) : 16 05 04: Gases in pressure containers (including halons) containing dangerous substances.

13.2. Additional information

: None.

SECTION 14. Transport information

UN number : 1072
Labelling ADR, IMDG, IATA



: 5.1 : Oxidizing substances
2.2 : Non-flammable, non-toxic gases

Land transport (ADR/RID)

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SECTION 14. Transport information (continued)

H.I. nr : 25
 UN proper shipping name : OXYGEN, COMPRESSED
 Transport hazard class(es) : 2
 Classification code : 1 O
 Packing group : -
 Packing Instruction(s) : P200
 Tunnel Restriction : E : Passage forbidden through tunnels of category E.
 Environmental hazards : None.

Sea transport (IMDG)

Proper shipping name : OXYGEN, COMPRESSED
 Class : 2.2
 Emergency Schedule (EmS) - Fire : F-C
 Emergency Schedule (EmS) - Spillage : S-W
 Packing instruction : P200
 IMDG-Marine pollutant : No

Air transport (ICAO-TI / IATA-DGR)

Proper shipping name (IATA) : OXYGEN, COMPRESSED
 Class : 2.2
 Passenger and Cargo Aircraft : Allowed.
 Packing instruction - Passenger and Cargo Aircraft : 200
 Cargo Aircraft only : Allowed.
 Packing instruction - Cargo Aircraft only : 200

Special precautions for user

: Avoid transport on vehicles where the load space is not separated from the driver's compartment.
 Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.
 Before transporting product containers:
 - Ensure that containers are firmly secured.
 - Ensure cylinder valve is closed and not leaking.
 - Ensure valve outlet cap nut or plug (where provided) is correctly fitted.
 - Ensure valve protection device (where provided) is correctly fitted.
 - Ensure there is adequate ventilation.
 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

EU legislation

Restrictions on use : None.
 Seveso directive 96/82/EC : Listed.

National legislation

National legislation : Ensure all national/local regulations are observed.

15.2. Chemical safety assessment

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SECTION 15. Regulatory information (continued)

: A CSA does not need to be carried out for this product.

SECTION 16. Other information

Indication of changes	: Revised safety data sheet in accordance with commission regulation (EU) No 453/2010.
Training advice	: Ensure operators understand the hazard of oxygen enrichment.
List of full text of R-phrases in section 3.	: R8 : Contact with combustible material may cause fire.
List of full text of H-statements in section 3.	: H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated.
Further information	: This Safety Data Sheet has been established in accordance with the applicable European Union legislation.
DISCLAIMER OF LIABILITY	: Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out. Details given in this document are believed to be correct at the time of going to press. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.

End of document

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SAFETY DATA SHEET

Issuing Date 03-Aug-2012

Revision Date 08-Jan-2016

Revision Number 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name Ozium Glycol-ized Air Sanitizer

Other means of identification

Product Code(s) OZ-1, OZ-22, OZ-23, OZ-31, OZ-62, OZ-15, OZM-1, OZM-22, OZM-23, OZM-31, 805539

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Air sanitizer

Uses advised against No information available

Supplier's details**Supplier Address**

Auto Expressions, LLC.
 505 E. Euclid
 Compton, CA 90224
 USA
 TEL: 877-572-2602/+1-310-639-0666

Emergency telephone number

Company Emergency Phone Number 877-675-7226 / +1-303-389-1658

2. HAZARDS IDENTIFICATION

Classification

This product is considered hazardous by the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Serious Eye Damage/Eye Irritation	Category 2
Skin Sensitization	Category 1
Specific Target Organ Systemic Toxicity (Single Exposure)	Category 3
Flammable aerosols	Category 1

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word Warning

Hazard Statements

- Causes serious eye irritation
- May cause an allergic skin reaction
- May cause drowsiness or dizziness
-
- Extremely flammable aerosol

**Appearance** Pale yellow.**Physical State** Aerosol.**Odor** Varies with fragrance.**Precautionary Statements****Prevention**

- Wash face, hands and any exposed skin thoroughly after handling.
- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Contaminated work clothing should not be allowed out of the workplace.
- Use only outdoors or in a well-ventilated area.
- 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.
- Wear protective gloves/protective clothing/eye protection/face protection.

General Advice

- None

Eyes

- 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.

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.

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.
- Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F

Disposal

- Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

2.4% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade secret
Isopropyl alcohol	67-63-0	40-50	*
Isobutane	75-28-5	24.18	*
Propane	74-98-6	5.82	*
Fragrance	Trade Secret	1-3	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	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.
Skin Contact	Rinse with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if exposed or you feel unwell.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects Rashes, Itching, Hives, Eye irritation/reactions. Drowsiness. Dizziness.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician May cause sensitization by skin contact. Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use: Water spray. Carbon dioxide (CO₂). Foam. Dry powder. Cool containers with flooding quantities of water until well after fire is out.

Unsuitable Extinguishing Media None

Specific Hazards Arising from the Chemical

Extremely flammable. Containers may explode when heated. Use water spray to cool unopened containers.

Explosion Data

Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	Yes.

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 Do not touch damaged packages or spilled material. In case of rupture: Remove all sources of ignition. Use personal protective equipment. Ensure adequate ventilation. Use only non-sparking tools. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Environmental Precautions	Prevent entry into waterways, sewers, basements or confined areas. See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Pick up and transfer to properly labeled containers. In case of rupture: Soak up with inert absorbent material. Use personal protective equipment. Non-sparking tools should be used. Sweep up and shovel into suitable containers for disposal.

7. HANDLING AND STORAGE**Precautions for safe handling**

Handling	Keep away from open flames, hot surfaces and sources of ignition. In case of rupture: Wear personal protective equipment. Ensure adequate ventilation. Take precautionary measures against static discharges. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities

Storage	Keep away from open flames, hot surfaces and sources of ignition. Store locked up. Protect from sunlight and store in well-ventilated place. Keep at temperatures below 50°C / 122°F.
Incompatible Products	Strong oxidizing agents. Acids.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control parameters****Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isobutane 75-28-5	TWA: 1000 ppm	N/A	N/A
Propane 74-98-6	TWA: 1000 ppm	TWA: 1000 ppm TWA: 1800 mg/m ³	IDLH: 2100 ppm TWA: 1000 ppm TWA: 1800 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	None under normal use conditions. Ensure that eyewash stations and safety showers are close to the workstation location.

Individual protection measures, such as personal protective equipment

Eye/Face Protection	None required for consumer use.
Skin and Body Protection	None required for consumer use. Wear protective gloves/clothing.
Respiratory Protection	None required under normal usage. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Respiratory protection must be provided in accordance with current local regulations.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical State	Aerosol.	Appearance	Pale yellow.
Odor	Varies with fragrance.	Odor Threshold	No information available.
<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>	
pH	No data available	None known	
Melting Point/Range	No data available	None known	
Boiling Point/Boiling Range	No data available	None known	
Flash Point	65 °C / 149 °F	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		
lower flammability limit	No data available		
Vapor Pressure	No data available	None known	
Vapor Density	No data available	None known	
Specific Gravity	No data available	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	
Viscosity	No data available	None known	
Flammable Properties	Not flammable		
Explosive Properties	No data available		
Oxidizing Properties	No data available		
<u>Other information</u>			
VOC Content (%)	55.6		

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition. Do not puncture or incinerate cans.

Incompatible materials

Strong oxidizing agents. Acids.

Hazardous decomposition products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	Product does not present an acute toxicity hazard based on known information
Inhalation	May cause drowsiness and dizziness.
Eye Contact	Causes serious eye irritation.
Skin Contact	May cause sensitization by skin contact.
Ingestion	Not an expected route of exposure.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Isopropyl alcohol	= 4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h
Isobutane	-	-	= 658 mg/L (Rat) 4 h
Propane	-	-	= 658 mg/L (Rat) 4 h

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Allergic skin reactions or irritation. Irritation May cause drowsiness and dizziness

Delayed and immediate effects and also 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
Isopropyl alcohol		Group 3		

IARC: (International Agency for Research on Cancer)

Group 3 - Not Classifiable as to its Carcinogenicity to Humans

Reproductive Toxicity	No information available.
STOT - single exposure	May cause drowsiness or dizziness
STOT - repeated exposure	No information available.
Aspiration Hazard	No information available.

Numerical measures of toxicity - Product

Acute Toxicity 2.4% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral	8961 mg/kg; Acute toxicity estimate
LD50 Dermal	24608 mg/kg; Acute toxicity estimate
gas	968028

12. ECOLOGICAL INFORMATION

Ecotoxicity

Not Classified

34.9 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)

Isopropyl alcohol 67-63-0	EC50 96 h: > 1000 mg/L (Desmodesmus subspicatus) EC50 72 h: > 1000 mg/L (Desmodesmus subspicatus)	LC50 96 h: = 11130 mg/L static (Pimephales promelas) LC50 96 h: = 9640 mg/L flow-through (Pimephales promelas) LC50 96 h: > 1400000 µg/L (Lepomis macrochirus)	EC50 48 h: = 13299 mg/L (Daphnia magna)

Persistence and Degradability No information available.

Bioaccumulation No information available.

Chemical Name	Log Pow
Isopropyl alcohol	0.05
Isobutane	2.88
Propane	2.3

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

14. TRANSPORT INFORMATION

DOT

Proper shipping name Consumer commodity
Hazard Class ORM-D
Description Consumer commodity, ORM-D
Emergency Response Guide Number 126

TDG

UN-Number UN1950
Proper Shipping Name Aerosols mixture
Hazard Class 2.1
Description UN1950, Aerosols mixture, 2.1, Limited Quantity

MEX

UN-Number UN1950
Proper Shipping Name Aerosols mixture
Hazard Class 2.1
Description UN1950, Aerosols mixture, 2.1, Limited Quantity

ICAO

UN-Number UN1950
Proper shipping name Aerosols mixture
Hazard Class 2.1
Description UN1950, Aerosols mixture, 2.1

IATA

UN-Number UN1950
Proper Shipping Name Aerosols, flammable mixture

Hazard Class	2.1
ERG Code	10L
Description	UN1950, Aerosols, flammable mixture, 2.1
<u>IMDG/IMO</u>	
UN-Number	UN1950
Proper Shipping Name	Aerosols mixture
Hazard Class	2
Subsidiary Class	See SP63
EmS No.	F-D, S-U
Description	UN1950, Aerosols mixture, 2.1 (See SP63), Limited Quantity
<u>RID</u>	
UN-Number	UN1950
Proper Shipping Name	Aerosols mixture
Hazard Class	2
Classification Code	5F
Description	UN1950, Aerosols mixture, 2.1, Limited Quantity
<u>ADR</u>	
UN-Number	UN1950
Proper Shipping Name	Aerosols mixture
Hazard Class	2
Classification Code	5F
Tunnel Restriction Code	(D)
Description	UN1950, Aerosols mixture, 2.1, (D), Limited Quantity
<u>ADN</u>	
UN-No	UN1950
Proper Shipping Name	Aerosols mixture
Hazard Class	2
Classification Code	5F
Special Provisions	190, 327, 344, 625
Description	UN1950, Aerosols mixture, 2.1, Limited Quantity
Limited Quantity	1 L
Ventilation	VE01, VE04

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	Complies
IECSC	-

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

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	Yes
Fire Hazard	Yes
Sudden Release of Pressure Hazard	Yes
Reactive Hazard	No

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.

U.S. 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	Illinois	Rhode Island
Isopropyl alcohol	X	X	X		X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazard	2	Flammability	2	Instability	0	Physical and Chemical Hazards	-
<u>HMIS</u>	Health Hazard	2*	Flammability	2	Physical Hazard	0	Personal Protection	X

*Indicates a chronic health hazard.

Prepared By Product Stewardship
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Latham, NY 12110
1-800-572-6501

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Revision Date 08-Jan-2016
Revision Note (M)SDS sections updated. 2.

General Disclaimer

The information provided on this SDS 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 Safety Data Sheet

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

SAFETY DATA SHEET

Professional Lysol® Brand III Kills 99.9% of Viruses & Bacteria** Disinfectant Spray,
All Scents



HEALTH • HYGIENE • HOME

1. Product and company identification

Product name : Professional Lysol® Brand III Kills 99.9% of Viruses & Bacteria** Disinfectant Spray, All Scents

Distributed by : Reckitt Benckiser LLC.
Morris Corporate Center IV
399 Interpace Parkway (P.O. Box 225)
Parsippany, New Jersey 07054-0225
+1 973 404 2600

Emergency telephone number (Medical) : 1-800-338-6167

Emergency telephone number (Transport) : 1-800-424-9300 (U.S. & Canada) CHEMTREC
Outside U.S. and Canada (North America), call Chemtrec:703-527-3887

Website: : <http://www.rbnainfo.com>

Product use : Disinfectant.

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS # : D0224478 v5.0

Formulation #: : 1338-022 (0175933) Original
1544-106 (0175940) Fresh
1338-019 (0175919) Country
1178-172 (0175917) Crisp Linen / Crystal Waters
1338-015 (0175918) Spring Waterfall
1338-026 (0175929) Early Morning Breeze / Lavender

EPA ID No. : 777-99-675

UPC Code / Sizes : 19 oz. Aerosol Cans
Original Scent, 36241-04650
Fresh, 36241-04675
Country Scent®, 36241-74276
Crisp Linen®, 36241-74828
Spring Waterfall®, 36241-76075
Crystal Waters, 36241-84044
Early Morning Breeze, 36241-81737
Lavender, 36241-89097

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

2. Hazards identification

Classification of the substance or mixture : FLAMMABLE AEROSOLS - Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : Flammable aerosol.
Pressurized container: may burst if heated.

Precautionary statements

General : Keep out of reach of children. 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. Pressurized container: Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source.

Response : Not applicable.

Storage : Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

Disposal : Not applicable.

Supplemental label elements : None known.

Hazards not otherwise classified : None known.

3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
Ethyl alcohol	30 - 60	64-17-5
butane	1 - 5	106-97-8
propane	< 2.5	74-98-6

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional 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.

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. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

4. First aid measures

Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin contact	: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	: Wash out mouth with water. Remove dentures if any. 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. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	: May cause eye irritation upon direct contact with eyes.
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	: Adverse symptoms may include the following: irritation redness
Inhalation	: Adverse symptoms may include the following: respiratory tract irritation coughing
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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : Flammable aerosol. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Gas may accumulate in low or confined areas or travel a considerable distance to a source of ignition and flash back, causing fire or explosion. Bursting aerosol containers may be propelled from a fire at high speed. Runoff to sewer may create fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

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. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

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, 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. In the case of aerosols being ruptured, care should be taken due to the rapid escape of the pressurized contents and propellant. If a large number of containers are ruptured, treat as a bulk material spillage according to the instructions in the clean-up section. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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 : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

6. Accidental release measures

- Large spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. 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.

7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing gas. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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 only non-sparking tools. Empty containers retain product residue and can be hazardous.

- Conditions for safe storage, including any incompatibilities** : Do not store above the following temperature: 50°C (122°F). Store in accordance with local regulations. Store away from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Use appropriate containment to avoid environmental contamination.

8. Exposure controls/personal protection

Control

Occupational exposure limits

Ingredient name	Exposure limits
Ethyl alcohol	ACGIH TLV (United States, 6/2013). STEL: 1000 ppm 15 minutes. OSHA PEL 1989 (United States, 3/1989). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 2/2013). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.
butane	OSHA PEL 1989 (United States, 3/1989). TWA: 800 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 800 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. ACGIH TLV (United States, 6/2013). STEL: 1000 ppm 15 minutes.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

8. Exposure controls/personal protection

propane

OSHA PEL 1989 (United States, 3/1989).

TWA: 1000 ppm 8 hours.

TWA: 1800 mg/m³ 8 hours.**NIOSH REL (United States, 10/2013).**

TWA: 1000 ppm 10 hours.

TWA: 1800 mg/m³ 10 hours.**OSHA PEL (United States, 2/2013).**

TWA: 1000 ppm 8 hours.

TWA: 1800 mg/m³ 8 hours.

- Appropriate engineering controls** : 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. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.
- 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.
- 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- 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. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.
- 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, 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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

9. Physical and chemical properties

Appearance

Physical state	: Liquid. [Aerosol.]
Color	: Clear.
Odor	: Characteristic.
Odor threshold	: Not available.
pH	: 10.8 to 11.8 [Conc. (% w/w): 100%]
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Closed cup: 25.6°C (78.1°F)
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: 0.8667 to 0.8967 g/cm ³ [20 to 25°C]
Solubility	: Easily soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

Aerosol product

Type of aerosol	: Spray
Heat of combustion	: 17.99 kJ/g
Ignition distance	: <45.72 cm

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	: Avoid all possible sources of ignition (spark or flame).
Incompatible materials	: Do not mix with household chemicals.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethyl alcohol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-
*Professional Lysol® Disinfectant Spray, All Scents (Aerosol)	LC50 Inhalation Vapor	Rat	>2.12 mg/l	4 hours Maximum attainable concentration

Conclusion/Summary : Not classified Harmful. *Information is based on toxicity test result of the concentrate of a similar product.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethyl alcohol	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 milligrams	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Eyes - Moderate irritant	Rabbit	-	100 microliters	-
	Eyes - Severe irritant	Rabbit	-	500 milligrams	-
	Skin - Mild irritant	Rabbit	-	400 milligrams	-
	Skin - Moderate irritant	Rabbit	-	24 hours 20 milligrams	-
*Professional Lysol® Disinfectant Spray, All Scents (Aerosol)	Eyes - Cornea opacity	Rabbit	< 1	72 hours	4 days
	Skin - Primary dermal irritation index (PDII)	Rabbit	0.3	4 hours	72 hours

Conclusion/Summary

Skin : Slightly irritating to the skin. *Information is based on toxicity test result of the concentrate of a similar product.

Eyes : Moderately irritating to eyes. *Information is based on toxicity test result of the concentrate of a similar product.

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
Ethyl alcohol	-	1	-

Reproductive toxicity

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

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 : May cause eye irritation upon direct contact with eyes.
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 : Adverse symptoms may include the following:
 irritation
 redness
Inhalation : Adverse symptoms may include the following:
 respiratory tract irritation
 coughing
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

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.

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Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

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.

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethyl alcohol	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franciscana - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC 4.995 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 0.375 µl/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks

Persistence and degradability

Not available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethyl alcohol	-0.35	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

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. Do not puncture or incinerate container.

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13. Disposal considerations

14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
DOT Classification	UN1950	Aerosols, flammable	2.1	-		Limited quantity
TDG Classification	UN1950	Aerosols, flammable	2.1	-		Limited quantity
Mexico Classification	UN1950	AEROSOL	2.1	-		Limited quantity
IMDG Class	UN1950	Aerosols, flammable	2.1	-		Limited quantity
IATA-DGR Class	UN1950	Aerosols, flammable	2.1	-		See DG List

PG* : Packing group

15. Regulatory information

U.S. Federal regulations : TSCA 8(a) PAIR: 2-methylpropan-2-ol
TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): All components are listed or exempted.
Clean Water Act (CWA) 311: ammonia
Clean Air Act (CAA) 112 regulated flammable substances: butane; propane

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 : Not listed

Composition/information on ingredients

No products were found.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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15. Regulatory information

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Fire hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Ethyl alcohol	30 - 60	Yes.	No.	No.	Yes.	No.

State regulations

Massachusetts : The following components are listed: ETHYL ALCOHOL; BUTANE; PROPANE

New York : None of the components are listed.

New Jersey : The following components are listed: ETHYL ALCOHOL; ALCOHOL; BUTANE; PROPANE

Pennsylvania : The following components are listed: DENATURED ALCOHOL; BUTANE; PROPANE

Label elements

Signal word: : CAUTION

Hazard statements : Causes moderate eye irritation

Precautionary measures : Do not get in eyes, on skin or on clothing. Wash thoroughly after handling. Wash with soap and water.

Keep out of the reach of children.

CONTENTS UNDER PRESSURE. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120 °F. Keep away from heat, sparks, open flames and hot surfaces. - No smoking.

Hazard statements :



Flammable

16. Other information

Hazardous Material Information System (U.S.A.) :

Health	1
Flammability	3
Physical hazards	0
Personal protection	B

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

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Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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16. Other information

National Fire Protection :
Association (U.S.A.)



NFPA (30B) aerosol Flammability Level 1

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

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

Date of issue : 26/06/2015.
Date of previous issue : 09/04/2015.
Version : 5
Prepared by : Reckitt Benckiser LLC.
Product Safety Department
1 Philips Parkway
Montvale, New Jersey 07646-1810 USA.
FAX: 201-476-7770

Revision comments : Revision as per US GHS. Correction to NFPA 30B level.

Indicates information that has changed from previously issued version.

Notice to reader

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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

16. Other information



RB is a member of the CSPA Product Care Product Stewardship Program.



Revision Number: 6

Prolia[®]

Safety Data Sheet

Date Issued 01-Feb-2013

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

1.1 Product identifier

Product Name: Prolia
Common Name: Denosumab
Chemical Name: Not Applicable
Synonyms: AMG 162, desnoumab

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

Recommended Use: Pharmaceutical
Uses advised against: No information available

Manufacturer:

Amgen Inc.
 One Amgen Center Drive
 Thousand Oaks, California 91320-1799
 1-805-447-7233
 1-805-447-1000

Emergency Telephone Number:

Chemtrec
 NORTH AMERICA 1-800-424-9300,
 INTERNATIONAL 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains denosumab, an active pharmaceutical ingredient for the treatment of bone diseases characterized by excessive bone resorption, including those from cancer-related bone destruction; treatment-related bone loss; and pathologic bone loss. The pharmacologic action of Prolia[®] appears to be reversible. Avoid inhalation, skin contact, eye contact, and accidental ingestion. Does not meet GHS classification criteria and therefore is not classified.

2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Not classified

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

2.2 Label elements

Not classified

2.3 Other Hazards

No information available



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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredients: Proprietary information

Chemical Name: Not Applicable

CAS-No: 615258-40-7

Each 1 mL single-use vial of Prolia[®] contains 60 mg denosumab (60mg/mL solution) and the following:

	CAS Number:	Amount
Sorbitol	50-70-4	4.7 %
Sodium acetate	127-09-3	17 mM
Water for Injection, USP	7732-18-5	---

Each 1 mL single-use prefilled syringe of Prolia[®] contains 60 mg denosumab (60mg/mL solution) and the following:

	CAS Number:	Amount
Sorbitol	50-70-4	4.7 %
Sodium acetate	127-09-3	17 mM
Water for Injection, USP	7732-18-5	---

4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye Contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. If symptoms persist, call a physician.

Ingestion: If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

Notes to Physician: Treat symptomatically.



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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Flammable Properties: Not applicable/aqueous solution.

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous Combustion Products: None

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Spill Procedures: If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Handling and Storage: Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 60 µg/m³ as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Prolia[®] has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m³ - 100 µg/m³).

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

8.2 Exposure controls

Personal Protective Equipment

Eye/face Protection: Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

Respiratory Protection: When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed.

Other: Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

8.3 Environmental exposure controls

Environmental Exposure Controls Avoid release to the environment.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear colorless to slightly yellow
Physical State:	Liquid
Molecular Weight:	147kD
Odor:	No information available
Odor Threshold:	No information available
pH:	5.2
Melting Point:	Not applicable
Flash Point:	Not applicable
Evaporation Rate:	No information available
Lower explosive limit:	No information available
Upper explosive limit:	No information available
Vapor Pressure:	No information available
Vapor Density (air = 1):	No information available
Relative density:	No information available
Water Solubility:	Not applicable
Partition Coefficient (log Kow):	No information available
Viscosity:	No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity	No information available
10.2 Chemical stability	Stable
10.3 Possibility of hazardous reactions	No information available
10.4 Conditions to avoid	No Information available
10.5 Incompatible materials	No information available
10.6 Hazardous decomposition products	No information available
10.7 Other information	None



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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity:	No information available
Skin corrosion/irritation:	No information available
Serious eye damage/eye irritation:	No information available
Respiratory or skin sensitization:	No information available
Germ cell mutagenicity:	No information available
Carcinogenicity:	No information available
Reproductive toxicity:	Even though this does not meet GHS classification, the following data is available: Prolia [®] exposure in cynomolgus monkeys by subcutaneous injection at 50 mg/kg from gestation day 20 to parturition resulted in increased fetal loss, stillbirths, and postnatal mortality, along with histological changes in infants. In general, the effects observed in mothers and infants were consistent with the pharmacological action of denosumab as a monoclonal antibody against RANKL and an inhibitor of osteoclastic bone resorption. No effects on male or female fertility have been observed.
STOT - single exposure:	No information available
STOT - repeated exposure:	Even though this does not meet GHS classification, the following data is available: Prolia [®] was administered to cynomolgus monkeys via subcutaneous injection once monthly for 1 year at doses of 1, 10 and 50 mg/kg and no adverse effects were observed. Denosumab produced rapid and sustained decreases in markers of bone turnover and increases in bone mineral density at doses >1 mg/kg, which were attributable to the pharmacologic activity of the monoclonal antibody.
Aspiration Hazard:	No information available



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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects: No information available

12.2 Persistence and degradability

Persistence/Degradability: No information available

12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation: No information available

12.4 Mobility in soil

Mobility in Environmental Media: No information available

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

12.6 Other adverse effects

Other Adverse Effects: No information available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Disposal Method: Dispose of any waste according to prescribed federal, state, local and competent authority guidelines.

14. TRANSPORT INFORMATION

DOT Not regulated by U.S. DOT or IATA



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15. REGULATORY INFORMATION

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

International Inventories

TSCA:	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS:	-
ENCS:	-
CHINA:	-
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

State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

15.2 Chemical safety assessment

No CSA has been conducted.



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16. OTHER INFORMATION

Text of R phrases mentioned in Section 2

No information available

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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 and protections, 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 because it may be biologically active.

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Promethazine HCl Injection, USP**hikma.**

Section 1. Identification

GHS product identifier	: Promethazine HCl Injection, USP
Synonyms	: Phenergan® (Promethazine HCl) Injection
Product code	: Not available.
Chemical family	: Anticholinergic Agent. Antihistaminic Agent. Antiemetic. Sedative.
Product type	: Regulated prescription drug.
Container information	: 1 mL vials or ampuls.
Identified uses	: Pharmaceutical.
Supplier's details	: Hikma Pharmaceuticals USA Inc. 246 Industrial Way West Eatontown, New Jersey (NJ) 07724
Emergency telephone number (with hours of operation)	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

Section 2. Hazards identification

OSHA/HCS status	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture	: SKIN SENSITIZATION - Category 1 AQUATIC HAZARD (LONG-TERM) - Category 3

GHS label elements

Hazard pictograms**Signal word**

: Warning

Hazard statements: May cause an allergic skin reaction.
Harmful to aquatic life with long lasting effects.

Precautionary statements

General

: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention

: Wear protective gloves. Avoid release to the environment. Avoid breathing vapor. Contaminated work clothing should not be allowed out of the workplace.

Response

: IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention.

Storage

: Not applicable.

hikma.**Promethazine HCl Injection, USP****Section 2. Hazards identification**

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Phenergan® (Promethazine HCl) Injection

CAS number/other identifiers

CAS number : Not applicable.

Product code : Not available.

Ingredient name	%	CAS number
Water	60 - 100	7732-18-5
Promethazine hydrochloride	1 - 5	58-33-3
Phenol	0.1 - 1	108-95-2
Disodium dihydrogen ethylenediaminetetraacetate	0 - 0.1	139-33-3
Sodium metabisulphite	0 - 0.1	7681-57-4
Calcium chloride	0 - 0.1	10043-52-4

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. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. 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. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed**Potential acute health effects**

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures**Extinguishing media**

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
Sulfur oxides
halogenated compounds

Section 5. Fire-fighting measures

- Special protective actions for fire-fighters** : No special measures are required.
- 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. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized 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). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and materials for containment and cleaning up

- 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. Wash spillages into an effluent treatment plant or proceed as follows. 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.

Section 7. Handling and storage**Precautions for safe handling**

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Avoid release to the environment. 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.
- 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. 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 protectionControl parametersOccupational 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.

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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

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, air-purifying or supplied air 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 propertiesAppearance

Physical state : Liquid. [Aqueous solution.]

Color : Colorless.

Odor : Not available.

Odor threshold : Not available.

pH : 4 to 5.5

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Section 9. Physical and chemical properties

Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor 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.

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	: Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis.
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

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Promethazine hydrochloride	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Section 11. Toxicological information

Information on the likely routes of exposure : Dermal contact. Eye contact. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact : May cause an allergic skin reaction.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : Adverse symptoms may include the following:
 irritation
 redness
Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
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

Route	ATE value
Oral	13333.3 mg/kg
Inhalation (vapors)	293.3 mg/L

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data 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 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. Care should be taken when handling empty containers that have not been cleaned or rinsed out. 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	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

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.

Section 14. Transport information

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) PAIR: Sodium Metabisulphite
 TSCA 8(a) CDR Exempt/Partial exemption: Not determined
 United States inventory (TSCA 8b): All components are listed or exempted.
 Clean Water Act (CWA) 307: Phenol
 Clean Water Act (CWA) 311: Phenol

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

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Phenol	0.1 - 1	Yes.	-	-	-	-

SARA 304 RQ : Not applicable.

SARA 311/312

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Promethazine hydrochloride	1 - 5	No.	No.	No.	Yes.	No.

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

No products were found.

International regulations

Section 15. Regulatory information

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. Malaysia Inventory (EHS Register): Not determined. New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted. Philippines inventory (PICCS): Not determined. Taiwan inventory (CSNN): Not determined.
Chemical Weapons Convention List Schedule I Chemicals	: Not listed
Chemical Weapons Convention List Schedule II Chemicals	: Not listed
Chemical Weapons Convention List Schedule III Chemicals	: Not listed

Section 16. Other information

History

Revision date mm/dd/yyyy	: 12/15/2018
Version	: 2
Prepared by	: KMK Regulatory Services Inc.
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

Notice to reader

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.



90126

SAFETY DATA SHEET

Issuing Date: 08-Apr-2019

Version 2

Modified HTF Medium HEPES with Gentamicin

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Modified HTF Medium HEPES with Gentamicin

Product code 90126

Product Use Laboratory chemicals.

Manufactured by

FUJIFILM Irvine Scientific, Inc.
2511 Daimler Street
Santa Ana, CA 92705
U.S.A.

SDSs are available at the following website(s): <http://www.irvinesci.com>

Company Phone Number Technical: 800-437-5706
Fax: 949-261-6522

Emergency Telephone Transport-CHEMTREC Inside NA: 800-424-9300
Transport-CHEMTREC Outside NA: 703-527-3887
Transport-CANUTEC Inside Canada: 613-996-6666
Medical Emergency (24 hour): 877-935-7387

E-mail tmrequest@irvinesci.com

2. HAZARDS IDENTIFICATION

Classification

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

GHS Label elements, including precautionary statements

Not classified

Precautionary Statements**Prevention**

Not applicable

Response

Not applicable

Storage

Not applicable

Disposal

Not applicable

Hazards not otherwise classified (HNOC)

Not classified

3. COMPOSITION/INFORMATION ON INGREDIENTS

The product contains no substances which at their given concentration, are considered to be hazardous to health.

4. FIRST AID MEASURES**First aid measures for different exposure routes****General advice**

Immediate medical attention is not required.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin contact

Wash off immediately with plenty of water. Get medical attention if irritation develops and persists.

Inhalation

Move to fresh air. If symptoms persist, call a physician.

Ingestion

If swallowed, do not induce vomiting - seek medical advice.

Most important symptoms/effects, acute and delayed

None known.

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

5. FIRE-FIGHTING MEASURES**Suitable Extinguishing Media**Dry chemical, CO₂, water spray or alcohol-resistant foam.**Unsuitable Extinguishing Media**

None known.

Specific hazards arising from the chemical

None known.

Hazardous Combustion Products

Carbon oxides. Sodium oxides. Hydrogen chloride.

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

Use personal protective equipment. Avoid contact with the skin and the eyes.

Environmental precautions

Prevent product from entering drains.

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Use personal protective equipment. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Clean contaminated surface thoroughly. After cleaning, flush away traces with water.

7. HANDLING AND STORAGE

Precautions for safe handling

Wear personal protective equipment. Avoid contact with skin, eyes or clothing. Avoid breathing vapors or mists. Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Keep at temperatures between 2 and 8 °C (35 and 46 °F).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Exposure controls

Engineering Measures 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.

Skin and body protection Wear protective gloves/clothing.

Respiratory protection	None required under normal usage. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.
General Hygiene Considerations	When using do not eat, drink or smoke. Take off contaminated clothing and wash before reuse. Regular cleaning of equipment, work area and clothing is recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	clear	Odor	Characteristic
Odor Threshold	Not available	Physical State @20°C	Liquid
pH	7.3 - 7.5	Molecular Weight	Not available
Specific Gravity	Not available	Autoignition temperature	Not available
Flash point	Not available	Boiling point / boiling range	Not available
Decomposition temperature	Not available	Freezing Point	Not available
Melting point / melting range	Not available		
Flammability Limit in Air	Not available		
Oxidizing Properties	Not available	Explosive Properties	Not available
Solubility	Not available	Partition coefficient	Not available
Evaporation rate	Not available	Vapor Pressure	Not available
Vapor density	Not available	Density	Not available
VOC (lb/gal)	Not available	VOC (g/l)	Not available
Dynamic viscosity	Not available		

10. STABILITY AND REACTIVITY

Reactivity

Stable under recommended storage conditions.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to Avoid

Freezing. Protect from light.

Incompatible Materials

Strong oxidizing agents. Strong acids. Strong bases.

Hazardous Decomposition Products

None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Acute toxicity

Inhalation	Non-irritating during normal use.
Eyes	Non-irritating during normal use.
Skin	Non-irritating during normal use.
Ingestion	Ingestion may cause stomach discomfort.

Component Information

No information available

Information on toxicological effects

No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation	Non-irritating during normal use.
Corrosivity	No information available.
Sensitization	No information available.
Mutagenic Effects	No information available.
Reproductive Toxicity	No information available.
Carcinogenicity	None known.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organ Effects None known.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

ATEmix (oral) >5000 mg/kg

ATE: Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods

Dispose of in accordance with local regulations.

Contaminated packaging

Do not re-use empty containers.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated.
<u>MEX</u>	Not regulated
<u>ICAO</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR/RID</u>	Not regulated
<u>ADN</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	No
DSL/NDSL	No
PICCS	No
EINECS/ELINCS	No
ENCS	No
IECSC	Yes
KECL	No
AICS	No

***Yes - All component(s) of this product are included or are exempt from listing on the inventory.**

***No - Indicates the component(s) of this product are either not listed or have not been determined to be listed on the inventory.**

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

U.S. Federal Regulations**TSCA Sections 4, 5 and 12(b)**

This product does not contain any chemicals regulated by TSCA Sections 4, 5 or 12(b).

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

Classification is shown in section 2 of this SDS

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.

U.S. State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

International Regulations**Canada - NDSL**

Chemical Name	NDSL
Sodium salt compound	X

Mexico - Grade

No information available

Mexico - Carcinogen Status and Exposure Limits

No information available

Other Regulations

No information available

90126 - Modified HTF Medium HEPES with Gentamicin

Revision Date 08-Apr-2019

16. OTHER INFORMATION

NFPA	Health Hazard 1	Flammability 1	Instability 0	Physical and chemical hazards -
HMIS	Health Hazard 1	Flammability 1	Physical Hazard 0	Personal protection B

Prepared By FUJIFILM Environment, Health and Safety, phone: 800-473-3854

Revision Date 08-Apr-2019

Revision Note No information available

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

	Sagent Pharmaceuticals, Inc.				
	Zoledronic Acid Injection			Safety Data Sheet (SDS)	
	SDS Issue Date: May 18, 2015	SDS No.: SDS 061	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 1 of 10

Section 1 - Identification

- (a) **Product Identifier:** Zoledronic Acid
- (b) **Product Code:** 25021-801, 25021-826
- Common/Trade Name:** Zometa[®]
- Chemical Name:** (1-Hydroxy-2-imidazol-1-yl-phosphonoethyl) phosphonic acid monohydrate
- Chemical Family:** Bisphosphonate
- (c) **Product Use:** Hypercalcaemia of Malignancy, tumor induced hypercalcemia
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial and Bag
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** **GHS Classification:**
Toxic to Reproduction, Category 2

NFPA Rating

Health Hazard	1
Fire Hazard	0
Reactivity Hazard	0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Signal Word:</u> <u>Symbol</u>	- WARNING 
H361fd	<u>GHS Hazard Statements:</u> - Suspected of damaging fertility. Suspected of damaging the unborn child.

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
P201 P202 P281 P308 + P313 P501	<u>GHS Precautionary Statements:</u> - Obtain special instructions before use. - Do not handle until all safety precautions have been read and understood - Use personal protective equipment as required - IF exposed or concerned: Get medical attention/advice - Dispose of contents/container in accordance with local/regional/national/international regulations

(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure		(c) CAS No.	(d) Impurities / Stabilizing Additives
		4 mg / 5mL vial	4 mg / 100mL bag		
(1-Hydroxy-2-imidazol-1-yl-phosphonoethyl) phosphonic acid monohydrate	Zoledronic Acid	0.08% (w/v)	0.004% (w/v)	118072-93-8	N/A
Sodium Chloride	Sodium Chloride	--	0.89% (w/v)	7647-14-5	N/A
(2R,3R,4R,5R)-Hexan-1,2,3,4,5,6-hexol	Mannitol	4.19% (w/v)	0.22% (w/v)	69-65-8	N/A
Sodium Citrate	Sodium Citrate	0.46% (w/v)	pH Adj.	6132-04-3	N/A
Water	Water for Injection	95.27% (w/v)	98.89% (w/v)	7732-18-5	N/A

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Section 4 - First Aid Measures

- Eye Exposure:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Exposure:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use carbon dioxide, dry chemical, or water spray
- (b) **Hazardous Combustion Products:** Fine particles (such as dust and mists) may fuel fires/explosions.
- (c) **Special Protective Equipment / Precautions:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Contain the source of the spill if it is safe to do so. Collect spilled material in a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Place waste in an appropriately labeled, sealed container for disposal.
- Large spills – non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
- Release to Air:** Care should be taken to avoid environmental release.

	Sagent Pharmaceuticals, Inc.				
	Zoledronic Acid Injection			Safety Data Sheet (SDS)	
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Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use appropriate personal protective equipment(PPE) while handling (see section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

Storage Conditions: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See Controlled Room Temperature]. Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Zoledronic Acid	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Citrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

(b) Engineering Controls

Ventilation: Engineering controls should be used as a primary means of control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits of $>1\mu\text{g}/\text{m}^3$ to $<10\mu\text{g}/\text{m}^3$

(c) Individual Protection Measures

Respiratory Protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

	Sagent Pharmaceuticals, Inc.				
	Zoledronic Acid Injection			Safety Data Sheet (SDS)	
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Eye Protection:	Wear safety glasses or goggles if eye contact is possible.
Skin Protection:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Other Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Additional Exposure Precautions:	Not applicable

Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear, colorless
(b)	Odor	Not Available
(c)	Odor Threshold	Not Available
(d)	pH	6.0-7.0
(e)	Melting Point:	Not Available
(f)	Initial Boiling Point:	Not Available
(g)	Flash Point	Not Available
(h)	Evaporation Rate:	Not Available
(i)	Flammability	Not Available
(j)	Upper Lower Flammability or Explosion Limits	Not Available
(k)	Vapor Pressure:	Not Available
(l)	Vapor Density:	Not Available
(m)	Relative Density	Not Available
(n)	Solubility(ies)	Highly Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not Available
(p)	Auto-ignition Temperature	Not Available
(q)	Decomposition Temperature	Not Available
(r)	Viscosity	Not Available

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Section 10 - Stability and Reactivity

(a)	Reactivity	Not Available
(b)	Chemical Stability	Stable under normal conditions of use.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	Protect from light and temperatures exceeding 86 °F (30 °C).
(e)	Incompatible Materials	As a precautionary measure, keep away from strong oxidizers.
(f)	Hazardous Decomposition Products	Carbon monoxide, carbon dioxide, formed under fire conditions

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin and eye contact, ingestion, inhalation
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Common adverse effects include nausea, vomiting, gastrointestinal irritation, fatigue, decreased red blood cell count (anemia), constipation, fever, shortness of breath (dyspnea) and bone pain.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	May damage fertility or unborn child.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Mouse	>10 mg/Kg
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Rat	>0.6 mg/Kg
Mannitol	LD ₅₀	Oral	Rat	13500 mg/kg
Mannitol	LD ₅₀	Oral	Mouse	22.00 g/kg

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

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Section 12 - Ecological Information

(a)	Ecotoxicity	Data is for drug substance and not finished product. <u><i>Daphnia Magna</i> (water flea) Toxicity</u> EC50 after 48 hrs: > 18 mg/L
(a)	Ecotoxicity	<u><i>Algae (selenastrum capricornutum)</i> Toxicity</u> EbC50 (72 hrs): 5.1 mg/L ErC50 (72 hrs): 15 mg/L NoEC (72 hrs): 2.2 mg/L <u>Bacterial Respiration (Activated Sludge) Inhibition:</u> EC50: 100 mg/L
(b)	Persistence and degradability	Data is for drug substance and not finished product. Degradation is 1-3% over a duration of 28 days
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available

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(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

DOT: Not regulated

ICAO/IATA: Not regulated

IMDG: Not regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 311/312 – Acute health effects, chronic health effects

SARA 313 – Not listed

OSHA Substance Specific - No

RCRA – Not listed

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.

1901 N. Roselle Rd, Suite 700

Schaumburg, IL 60195

847-908-1600

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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity

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RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

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REMICADE

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SECTION 1. IDENTIFICATION

Product name : REMICADE
 Substance name : REMICADE 100mg lyophilized powder for IV infusion
 infliximab

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
 Titusville NJ 08560
 US

Telephone : (609) 730-2000

Emergency telephone number : +32 14 60 24 44

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
 Large Molecule Pharmaceutical intended for medical use
 Pharmacotherapeutic group: Immunosuppressive agents
 This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
 This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible persons.

This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate

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the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.
 The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
 16.42 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Infliximab	170277-31-3	>= 10 - < 20

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
 Artificial respiration and/or oxygen may be necessary.
 Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
 Wash off with plenty of water.
 If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
 for at least 5 minutes.
 Remove contact lenses.
 If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
 Call a physician immediately.

Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

Notes to physician : Treat symptomatically.
 Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : Water spray jet

Specific hazards during fire-fighting : Heating can release hazardous gases.

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Hazardous combustion products : No hazardous combustion products are known

Further information : Avoid dust formation.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Evacuate personnel to safe areas.
In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Avoid breathing dust.
Avoid dust formation.
Do not break, crush or spill this Finished Pharmaceutical Product.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Clean up with soap and water or a solution containing at least 10% sodium hypochlorite (1 part sodium hypochlorite ("Bleach"), mixed with 9 parts water) is recommended for cleaning of surfaces and equipment.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust.
Keep in properly labelled containers.
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.

Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations.
To avoid thermal decomposition, do not overheat.
For personal protection see section 8.
Avoid creating dust.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
Do not break, crush or spill this Finished Pharmaceutical Product.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.

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Store in original container.
 Keep containers tightly closed in a dry, cool and well-ventilated place.
 Keep away from heat and sources of ignition.
 Keep locked up.

Recommended storage temperature : 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Infliximab	170277-31-3	PBOEL-HHC	2	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2. This means that the OEL is estimated to be from 20 to 100 µg/m ³			
		TWA	0.028 mg/m ³	J&J OEL/PBOEL HHC
	Further information: Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.			

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
 Engineering controls should always be the primary method of controlling exposures.
 If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

Hand protection

Remarks : No special precautions required.

Eye protection : No special precautions required.

Skin and body protection : No special precautions required.

Protective measures : The type of protective equipment must be selected based on

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the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder, (lyophilised), Vial
Colour	: white
Odour	: No data available
Odour Threshold	: No data available
pH	: 7.2
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No information available.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: No data available
Solubility in other solvents	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Explosive properties	: No data available

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Oxidizing properties : No data available

Sublimation point : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

Components:**Infliximab**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

Skin corrosion/irritation**Product:**

Remarks: No data available

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Components:**Infliximab**

Remarks: No data available

Serious eye damage/eye irritation**Product:**

Remarks: No data available

Components:**Infliximab**

Remarks: No data available

Respiratory or skin sensitisation**Product:**

Remarks: No data available

Components:**Infliximab**

Remarks: May cause sensitisation of susceptible persons.

Germ cell mutagenicity**Product:**

Genotoxicity in vitro : Remarks: No data available

Components:**Infliximab**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
 Species: Human lymphocytes
 Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Test Type: In vivo micronucleus test
 Result: In vivo tests did not show any chromosomal changes.

Test Type: in vivo assay
 Result: In vivo tests did not show any chromosomal changes.

Carcinogenicity**Product:**

Remarks: No data available

Components:**Infliximab**

Species: Mouse

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Exposure time: 6 months
 Dose: 10 - 40 mg/kg
 Remarks: Did not show carcinogenic effects in animal experiments.

IARC	No component 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 component 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 component 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**Product:**

Effects on fertility :
 Remarks: No data available

Effects on foetal development : Remarks: No data available

Components:**Infliximab**

Effects on fertility :
 Species: Mouse
 Dose: > 40 mg/kg
 Remarks: No adverse effects on sexual function and fertility.

Effects on foetal development : Remarks: No data available

STOT - single exposure**Product:**

Remarks: No data available

Components:**Infliximab**

Remarks: No data available

STOT - repeated exposure

No data available

Repeated dose toxicity**Product:**

Species: Mouse
 10 - 40 mg/kg
 Exposure time: 6 months

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Remarks: No adverse effect has been observed in chronic toxicity tests.

Components:**Infliximab**

Remarks: No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Components:**Infliximab**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Persistence and degradability**Product:**

Biodegradability : Remarks: No data available

Components:**Infliximab**

Biodegradability : Remarks: No data available

Bioaccumulative potential**Product:**

Bioaccumulation : Remarks: No data available

Components:**Infliximab**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

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Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
manufactured with a Class I or Class II ODS as defined by the
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +
B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regula-
tions.

Contaminated packaging : Empty containers should be taken to an approved waste han-
dling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International transport regulations****ADR**

Not dangerous goods

RID

Not dangerous goods

DOT

Not dangerous goods

IATA

Not dangerous goods

IMDG

Not dangerous goods

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**

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SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Massachusetts Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	70 - 90 %

Pennsylvania Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	70 - 90 %
Infliximab	170277-31-3	10 - 20 %

New Jersey Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	70 - 90 %
Infliximab	170277-31-3	10 - 20 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations

: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
For professional users only.

This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

The components of this product are reported in the following inventories:

REACH : Not in compliance with the inventory

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	: alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	: Infliximab
CH INV	: Not in compliance with the inventory
	: alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	: Infliximab
TSCA	: Not On TSCA Inventory
	: Infliximab
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	: Infliximab
AICS	: Not in compliance with the inventory
	: Infliximab
NZIoC	: Not in compliance with the inventory
	: Infliximab
ENCS	: Not in compliance with the inventory
	: alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	: Infliximab
ISHL	: Not in compliance with the inventory
	: alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	: Infliximab
KECI	: Not in compliance with the inventory
	: Infliximab
PICCS	: Not in compliance with the inventory
	: Infliximab
IECSC	: Not in compliance with the inventory
	: Infliximab

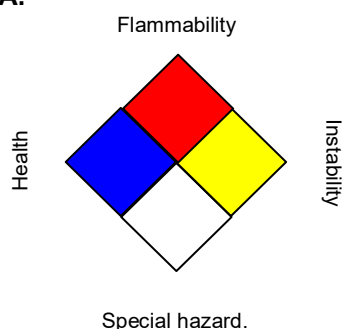
Inventories

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AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2015/04/21

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	1,234,567.89

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.

US / EN

Safety Data Sheet

RITUXAN(R) Vials (100 mg/10 ml)**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product name RITUXAN(R) Vials (100 mg/10 ml)

Product code SAP-10063468

Synonyms - Rituxan *1

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

- pharmaceutical active substance (antineoplastic)
- pharmaceutical active substance (antirheumatic)

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	Local representation:

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

*1 referring to: Rituximab

SECTION 2: Hazards identification**Classification of the substance or mixture / Label elements**

GHS Classification no classification and labelling according to GHS

Other hazards

Note - no information available

RITUXAN(R) Vials (100 mg/10 ml)

SECTION 3: Composition/information on ingredients

Characterization chimeric monoclonal antibody (rituximab) with excipients

Ingredients	Concentration	GHS-Classification (pure ingredient)

Rituximab 174722-31-7	1 %	

***1** referring to: Rituximab

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note - no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician - treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

RITUXAN(R) Vials (100 mg/10 ml)

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - ensure adequate ventilation

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - rinse with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass, polyethylene, PVC

Note - no incompatibilities between Rituxan and polyvinylchloride or polyethylene bags have been observed
 - do not shake the solution

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
 - protected from light
 - do not freeze

Validity - 30 months, 2 to 8 °C, see expiry date on the label

Packaging materials - keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.04 mg/m³ *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
 - Respiratory protection is recommended for dusty operations.

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

RITUXAN(R) Vials (100 mg/10 ml)

Eye protection - safety glasses

*1 referring to: Rituximab

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Color colorless, clear

Form sterile liquid

pH value 6.5

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - do not shake the solution, formation of foam

RITUXAN(R) Vials (100 mg/10 ml)

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity	- MTD	> 100	mg/kg	(i.v., cynomolgus monkey)	*1
	- MTD	> 100	mg/kg	(i.p., mouse)	*1
Sensitization	- anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described				
Note	- side effect(s) during therapy: tumor lysis syndrome, allergic symptoms, respiratory disorders, cardiac arrhythmias, hypotension, changes in blood count, vomiting, urticaria, fever, shivering, nausea, headache, kidney damages - chimeric humanized monoclonal antibody that binds to CD20, a protein present on the cell surface of pre-B- and mature B-lymphocytes				
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Carcinogenicity: formulation not listed by NTP, IARC or OSHA				
*1	referring to:	Rituximab			

SECTION 12: Ecological information**12.1. Toxicity**

Ecotoxicity	- monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected	*1

12.2. Persistence and degradability

Ready biodegradability	- globular proteins are generally well biodegradable	*1

12.3. Bioaccumulative potential

Note	- no information available

12.4. Mobility in soil

Note	- no information available

12.5. Results of PBT and vPvB assessment

Note	- no information available

RITUXAN(R) Vials (100 mg/10 ml)**12.6. Other adverse effects**

Note - no information available

***1** referring to: Rituximab

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
 - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
 - State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 2, 3, 16

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.



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* 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;



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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]



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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).



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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 soiled 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



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@ 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 - <u>Category:</u> <u>4</u>	2,000.00, Rat - <u>Category:</u> 4	2.00, Rat - <u>Category:</u> <u>2</u>	No data <u>available</u>	No data <u>available</u>

Note: When no route 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).



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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
<u>Aspiration hazard</u>	---	<u>Not Applicable</u>

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 <u>mykiss</u>	2.32 , Daphnia magna	0.71 (72 hr), Microcystis <u>pulverea ssp. incerta</u>

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.



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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%):



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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.

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1.18	2015/04/21	100000008610	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Product name : SIMPONI
 Substance name : SIMPONI PFS prefilled syringe
 CNTO 148
 golimumab

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
 Titusville NJ 08560
 US

Telephone : (609) 730-2000

Emergency telephone number : +32 14 60 24 44

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
 Large Molecule Pharmaceutical intended for medical use
 Pharmacotherapeutic group: Immunosuppressive agents
 This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
 This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible persons.
 This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.
 Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

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Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 42 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Sucrose	57-50-1	>= 10 - < 20
GOLIMUMAB	Not Assigned	>= 5 - < 10

SECTION 4. FIRST AID MEASURES

If inhaled	: If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	: Take off contaminated clothing and shoes immediately. Wash off with plenty of water. If symptoms persist, call a physician.
In case of eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.
If swallowed	: If swallowed, rinse mouth with water (only if the person is con- scious). Call a physician immediately.
Most important symptoms and effects, both acute and delayed	: Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Notes to physician	: Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment.
Unsuitable extinguishing media	: Water spray jet
Specific hazards during fire- fighting	: No information available.

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Hazardous combustion products : No hazardous combustion products are known

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Evacuate personnel to safe areas.
Do not break, crush or spill this Finished Pharmaceutical Product.

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
Clean up with soap and water or a solution containing at least 10% sodium hypochlorite (1 part sodium hypochlorite ("Bleach"), mixed with 9 parts water) is recommended for cleaning of surfaces and equipment.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Not applicable

Advice on safe handling : To avoid thermal decomposition, do not overheat.
For personal protection see section 8.
Avoid inhalation, ingestion and contact with skin and eyes.
Do not break, crush or spill this Finished Pharmaceutical Product.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.

Recommended storage temperature : 2 - 8 °C

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
			10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
GOLIMUMAB	Not Assigned	PBOEL-HHC	2	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2.				

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
 Engineering controls should always be the primary method of controlling exposures.
 If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

Hand protection

Remarks : No special precautions required.

Eye protection : No special precautions required.

Skin and body protection : No special precautions required.

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance

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at the specific workplace.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: solution, Prefilled syringe
Colour	: clear, light yellow, opalescent
Odour	: No data available
Odour Threshold	: No data available
pH	: 5 - 7.2
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No information available.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available

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Explosive properties	:	Not explosive (not expected to be explosive based on components)
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Exposure to light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

Components:**Sucrose**

Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg

LD50:

GOLIMUMAB

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

Acute toxicity (other routes of administration)	:	(Monkey): 50 mg/kg Application Route: intravenous injection Remarks: No adverse effect has been observed in acute toxicity tests.

	:	(Monkey): 50 mg/kg Application Route: Subcutaneous; injection made in the back

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or neck of animal
Remarks: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation**Product:**

Remarks: No data available

Components:**GOLIMUMAB**

Remarks: No data available

Serious eye damage/eye irritation**Product:**

Remarks: No data available

Components:**GOLIMUMAB**

Remarks: No data available

Respiratory or skin sensitisation**Product:**

Remarks: No data available

Germ cell mutagenicity**Product:**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Components:**GOLIMUMAB**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity**Product:**

Remarks: No data available

Components:**GOLIMUMAB**

Remarks: No data available

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IARC	No component 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 component 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 component 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**Product:**

Effects on fertility	:	Remarks: No data available

Effects on foetal development	:	Remarks: No data available

Components:**GOLIMUMAB**

Effects on fertility	:	NOAEL: 50 mg/kg, Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction. No embryotoxic effects have been observed in animal tests.

Effects on foetal development	:	Remarks: Did not show teratogenic effects in animal experiments.

STOT - single exposure**Product:**

Remarks: Even though this does not meet GHS classification, inhalation of aerosol/dust from an acute exposure or significant overexposure may cause autoantibody formation or allergies.

Components:**GOLIMUMAB**

Remarks: Even though this does not meet GHS classification, inhalation of aerosol/dust from an acute exposure or significant overexposure may cause autoantibody formation or allergies.

STOT - repeated exposure**Product:**

Remarks: No data available

Repeated dose toxicity**Product:**

Species: human

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Application Route: intravenous injection
 Dose: 0,1-10
 Remarks: No adverse effect has been observed in chronic toxicity tests.

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Toxicity to bacteria : Remarks: No data available

Components:**GOLIMUMAB**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Persistence and degradability**Product:**

Biodegradability : Remarks: No data available

Components:**GOLIMUMAB**

Biodegradability : Remarks: No data available

Bioaccumulative potential**Product:**

Bioaccumulation : Remarks: No data available

Components:**Sucrose**

Partition coefficient: n-octanol/water : log Pow: -3.67

GOLIMUMAB

Bioaccumulation : Remarks: No data available

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Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
manufactured with a Class I or Class II ODS as defined by the
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +
B).

Additional ecological : Should not be released into the environment.
information

Components:**GOLIMUMAB**

Additional ecological : There is no data available for this product.
information : Should not be released into the environment.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regula-
tions.

Contaminated packaging : Empty containers should be taken to an approved waste han-
dling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International transport regulations****ADR**

Not dangerous goods

RID

Not dangerous goods

DOT

Not dangerous goods

IATA

Not dangerous goods

IMDG

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Not dangerous goods

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

Sucrose	57-50-1	10 - 20 %

Pennsylvania Right To Know

	Not Assigned	10 - 20 %
Sorbitol, L-Bio	50-70-4	10 - 20 %
Sucrose	57-50-1	10 - 20 %
Golimumab	Not Assigned	5 - 10 %

New Jersey Right To Know

	Not Assigned	10 - 20 %
Sorbitol, L-Bio	50-70-4	10 - 20 %
Sucrose	57-50-1	10 - 20 %
Golimumab	Not Assigned	5 - 10 %
	Not Assigned	1 - 5 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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Other regulations : According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

The components of this product are reported in the following inventories:

REACH : Not in compliance with the inventory

:

:

: SORBITOL, L-BIO

: Sucrose

:

: GOLIMUMAB

CH INV : Not in compliance with the inventory

:

:

: SORBITOL, L-BIO

: Sucrose

:

: GOLIMUMAB

TSCA : Not On TSCA Inventory

:

: GOLIMUMAB

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

:

: GOLIMUMAB

AICS : Not in compliance with the inventory

:

: GOLIMUMAB

NZIoC : Not in compliance with the inventory

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	:
	: GOLIMUMAB
ENCS	: Not in compliance with the inventory
	:
	: Sucrose
	:
	: GOLIMUMAB
ISHL	: Not in compliance with the inventory
	:
	: Sucrose
	:
	: GOLIMUMAB
KECI	: Not in compliance with the inventory
	:
	: GOLIMUMAB
PICCS	: Not in compliance with the inventory
	:
	: GOLIMUMAB
IECSC	: Not in compliance with the inventory
	:
	: GOLIMUMAB

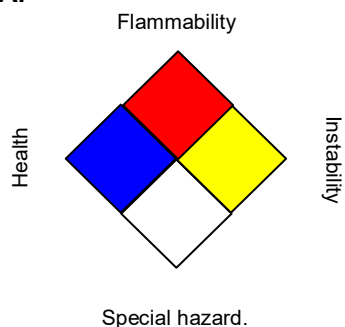
Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

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SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 = Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

Revision Date : 2015/04/21

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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.

US / EN

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SECTION 1. IDENTIFICATION

Product name : SIMPONI ARIA
 Substance name : SIMPONI ARIA
 CNTO 148 antibody
 golimumab

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
 Titusville NJ 08560
 US

Telephone : (609) 730-2000

Emergency telephone number : +32 14 60 24 44

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
 Large Molecule Pharmaceutical intended for medical use
 Pharmacotherapeutic group: Immunosuppressive agents
 This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
 This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Other hazards

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible persons.

This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

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This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible persons.

This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 97.63 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Sorbitol	50-70-4	>= 70 - < 90
GOLIMUMAB	Not Assigned	>= 20 - < 30

SECTION 4. FIRST AID MEASURES

If inhaled	: If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	: Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water. If symptoms persist, call a physician.
In case of eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.
If swallowed	: If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.
Most important symptoms and effects, both acute and delayed	: Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Notes to physician	: Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Carbon dioxide (CO₂)

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Sand
Foam
Dry powder
Water mist
Aqueous film forming foam (AFFF).

Unsuitable extinguishing media : Water spray jet

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Evacuate personnel to safe areas.
Do not break, crush or spill this Finished Pharmaceutical Product.

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material.
Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
Clean up with soap and water or a solution containing at least 10% sodium hypochlorite (1 part sodium hypochlorite ("Bleach"), mixed with 9 parts water) is recommended for cleaning of surfaces and equipment.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Not applicable

Advice on safe handling : To avoid thermal decomposition, do not overheat.
Avoid inhalation, ingestion and contact with skin and eyes.
For personal protection see section 8.
Do not break, crush or spill this Finished Pharmaceutical Product.

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Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.

Recommended storage temperature : 2 - 8 °C

Storage period : 24 Months

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
GOLIMUMAB	Not Assigned	PBOEL-HHC	2	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2.				

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

Hand protection

Remarks : No special precautions required.

Eye protection : No special precautions required.

Skin and body protection : No special precautions required.

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: solution, Vial
Colour	: clear, to, opalescent colourless, to, light yellow
pH	: 5.5
Flash point	: No data available
Vapour pressure	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: None reasonably foreseeable.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
Conditions to avoid	: To avoid thermal decomposition, do not overheat. Protect from frost. Exposure to sunlight.
Incompatible materials	: None known.
Hazardous decomposition products	: None known.

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Components:**Sorbitol**

Acute oral toxicity : LD50 (Rat): 15,900 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

GOLIMUMAB

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : (Monkey): 50 mg/kg
 Application Route: intravenous injection
 Remarks: No adverse effect has been observed in acute toxicity tests.

(Monkey): 50 mg/kg
 Application Route: Subcutaneous; injection made in the back or neck of animal
 Remarks: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation**Product:**

Remarks: No data available

Components:**Sorbitol**

Remarks: No data available

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Remarks: No data available

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Serious eye damage/eye irritation**Product:**

Remarks: No data available

Components:**Sorbitol**

Remarks: No data available

GOLIMUMAB

Remarks: No data available

Respiratory or skin sensitisation**Product:**

Remarks: May cause sensitization by inhalation.

Components:**Sorbitol**

Remarks: No data available

Germ cell mutagenicity**Product:**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects.

Components:**Sorbitol**

Genotoxicity in vitro : Remarks: No data available

Germ cell mutagenicity - Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

GOLIMUMAB

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity**Product:**

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

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Components:**Sorbitol**

Remarks: No data available

GOLIMUMAB

Remarks: No data available

IARC

No component 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 component 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 component 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**Product:**

Effects on fertility

:

Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Teratogenicity - Assessment

:

Animal testing did not show any effects on foetal development.

Components:**Sorbitol**

Effects on fertility

:

Remarks: No data available

Effects on foetal development

:

Remarks: No data available

GOLIMUMAB

Effects on fertility

:

NOAEL: 50 mg/kg,
 Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.
 No embryotoxic effects have been observed in animal tests.

Effects on foetal development

:

Remarks: Did not show teratogenic effects in animal experiments.

STOT - single exposure**Product:**

Remarks: Even though this does not meet GHS classification, inhalation of aerosol/dust from an

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acute exposure or significant overexposure may cause autoantibody formation or allergies.

Components:**Sorbitol**

Remarks: No data available

GOLIMUMAB

Remarks: Even though this does not meet GHS classification, inhalation of aerosol/dust from an acute exposure or significant overexposure may cause autoantibody formation or allergies.

STOT - repeated exposure

No data available

Repeated dose toxicity**Components:****Sorbitol**

Remarks: No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Toxicity to bacteria : Remarks: No data available

Components:**Sorbitol**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

GOLIMUMAB

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

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Persistence and degradability**Product:**

Biodegradability : Remarks: No data available

Components:**Sorbitol**

Biodegradability : Remarks: Expected to be biodegradable

GOLIMUMAB

Biodegradability : Remarks: No data available

Bioaccumulative potential**Product:**

Bioaccumulation : Remarks: No data available

Components:**Sorbitol**Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.
No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -2.20

GOLIMUMAB

Bioaccumulation : Remarks: No data available

Mobility in soil**Product:**

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

Environmental fate and pathways : Remarks: No data available

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : Should not be released into the environment.

Components:**GOLIMUMAB**

Additional ecological : There is no data available for this product.

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information

Should not be released into the environment.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International transport regulations****ADR**

Not dangerous goods

RID

Not dangerous goods

DOT

Not dangerous goods

IATA

Not dangerous goods

IMDG

Not dangerous goods

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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SIMPONI ARIA

Version	Revision Date:	SDS Number:	Date of last issue: 2015/03/20
1.30	2015/04/21	100000009560	Date of first issue: 2013/12/23

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Sorbitol	50-70-4	70 - 90 %
GOLIMUMAB	Not Assigned	20 - 30 %

New Jersey Right To Know

Sorbitol	50-70-4	70 - 90 %
GOLIMUMAB	Not Assigned	20 - 30 %
L-Histidine, monohydrochloride, monohydrate	5934-29-2	1 - 5 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations

: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

The components of this product are reported in the following inventories:

REACH	: Not in compliance with the inventory
	:
	:
	: GOLIMUMAB
	: Sorbitol
	: L-Histidine, monohydrochloride, monohydrate
CH INV	: Not in compliance with the inventory
	:

SAFETY DATA SHEET

SIMPONI ARIA

Version 1.30	Revision Date: 2015/04/21	SDS Number: 100000009560	Date of last issue: 2015/03/20 Date of first issue: 2013/12/23

	:
	: GOLIMUMAB
	: Sorbitol
	: L-Histidine, monohydrochloride, monohydrate
TSCA	: Not On TSCA Inventory
	: GOLIMUMAB
	: L-Histidine, monohydrochloride, monohydrate
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	: GOLIMUMAB
	: L-Histidine, monohydrochloride, monohydrate
AICS	: Not in compliance with the inventory
	: GOLIMUMAB
NZIoC	: Not in compliance with the inventory
	: GOLIMUMAB
ENCS	: Not in compliance with the inventory
	:
	: GOLIMUMAB
	: L-Histidine, monohydrochloride, monohydrate
ISHL	: Not in compliance with the inventory
	:
	: GOLIMUMAB
	: L-Histidine, monohydrochloride, monohydrate
KECI	: Not in compliance with the inventory
	: GOLIMUMAB
	: L-Histidine, monohydrochloride, monohydrate
PICCS	: Not in compliance with the inventory
	: GOLIMUMAB

SAFETY DATA SHEET

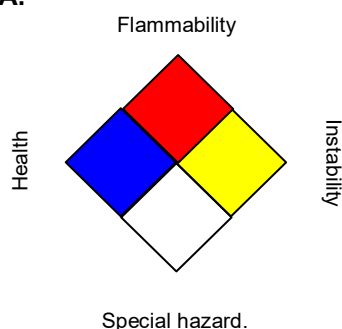
SIMPONI ARIA

Version 1.30	Revision Date: 2015/04/21	SDS Number: 100000009560	Date of last issue: 2015/03/20 Date of first issue: 2013/12/23

IECSC : Not in compliance with the inventory
: GOLIMUMAB

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2015/04/21

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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.

US / EN



B. Braun Medical Inc.
824 12th Avenue
Bethlehem, PA 18018

Telephone: (610) 691-5400
Fax: (610) 691-2202

Dear Valued Customer:

You requested a safety data sheet for Sodium Chloride Injections distributed by B. Braun. The product codes are as follows:

Reference Number	Container Type	Size (mL)
L8020	EXCEL [®]	1000
L8021	EXCEL	500
L8000	EXCEL	1000
L8001	EXCEL	500
L8002	EXCEL	250
S8004-5264	PAB [®]	100mL fill in 150mL
S8004-5384	PAB	50mL fill in 100mL
S8004-5410	PAB	25mL fill in 100mL
L8051	EXCEL	500
L8061	EXCEL	500

We are pleased to inform you that this particular B. Braun product does not contain any hazardous chemicals or harmful physical agents as defined by the Hazard Communication Standard (29 CFR1910.1200).

This information is provided independently of any sale of product and is not intended to constitute product performance information. No express or implied warranty of any kind is made with respect to the product, underlying data or the information contained herein. Further, this information is not intended to provide specialist advice or instructions regarding the products and services sold by B. Braun.

If further assistance is needed, please call our Clinical and Technical Support department at (800) 854-6851.

Sincerely,

Clinical & Technical Support

Baxter

Product Name: 0.9% SODIUM CHLORIDE INJECTION, USP

Product Code: 1A1322, 1A1323, 2B0042, 2B0043, 2B1300, 2B1301, 2B1302, 2B1306, 2B1307, 2B1308, 2B1309, 2B1321, 2B1322Q, 2B1323Q, 2B1324, 4R2180T, 4R2182, 4R2310, 4R2312, 6E1322, 6E1323, 6E1324, FE1323, FE1324D

Rev. Date: 8/12/2014

Based upon the Occupational Safety & Health Administration (OSHA) Hazard Communication 29 CFR 1910.1200, this product is not considered hazardous and a Material Safety Data Sheet (MSDS) is not required.

We value your business and will make every effort to supply you with the information needed to train your employees to work safely with Baxter Products. Should you need additional information, please feel free to contact us at the Center for One Baxter.

PHONE: 800-422-9837 (8 A.M. TO 5 P.M. CENTRAL STANDARD TIME)

FAX: 224-948-3642

EMAIL: ONEBAXTER@BAXTER.COM

ADDRESS: CENTER FOR ONE BAXTER
ONE BAXTER PARKWAY
DF4-1W
DEERFIELD, IL 60015



SAFETY DATA SHEET

Revision date: 25-Oct-2016

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
 275 North Field Drive
 Lake Forest, Illinois 60045
 1-800-879-3477

Hospira UK Limited
 Horizon
 Honey Lane
 Hurley
 Maidenhead, SL6 6RJ
 United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
 Revision date: 25-Oct-2016

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	0.45-0.9
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES**Description of First Aid Measures**

Eye Contact: Due to the nature of this material first aid is not normally required.

Skin Contact: Due to the nature of this material first aid is not normally required.

Ingestion: Due to the nature of this material first aid is not normally required.

Inhalation: Not an expected route of exposure.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Not applicable

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

Not applicable

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Not applicable

Environmental Precautions

None

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Wipe up with a damp cloth and place in container for disposal.

Additional Consideration for Large Spills: None

7. HANDLING AND STORAGE

Precautions for Safe Handling

No special handling requirements for normal use of this material.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: None

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM CHLORIDE

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³

Australia PEAK 2 mg/m³

Austria OEL - MAKs 2 mg/m³

Bulgaria OEL - TWA 2.0 mg/m³

Czech Republic OEL - TWA 1 mg/m³

Estonia OEL - TWA 1 mg/m³

France OEL - TWA 2 mg/m³

Greece OEL - TWA 2 mg/m³

Hungary OEL - TWA 2 mg/m³

Japan - OELs - Ceilings 2 mg/m³

Latvia OEL - TWA 0.5 mg/m³

OSHA - Final PELs - TWAs: 2 mg/m³

Poland OEL - TWA 0.5 mg/m³

Slovakia OEL - TWA 2 mg/m³

Slovenia OEL - TWA 2 mg/m³

Sweden OEL - TWAs 1 mg/m³

Switzerland OEL - TWAs 2 mg/m³

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
Revision date: 25-Oct-2016

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m ³
Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	5 ppm 8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Exposure Controls

Engineering Controls:
Personal Protective Equipment:

Engineering controls should be used as the primary means to control exposures. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Not required for the normal use of this product.
Eyes: Not required under normal conditions of use.
Skin: Not required for the normal use of this product.
Respiratory protection: None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Colorless
Odor:	None	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 4.5-7.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

SODIUM HYDROXIDE

No data available

SODIUM CHLORIDE

No data available

Water for injection

No data available

HYDROCHLORIC ACID

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: None
Incompatible Materials: None
Hazardous Decomposition Products: No data available

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Mild eye irritant in experimental animals (based on components)

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3g/kg

Mouse Oral LD 50 4g/kg

Rabbit Dermal LD 50 > 10g/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6

SAFETY DATA SHEET

Material Name: Sodium Chloride Irrigation (Hospira, Inc.)
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15. REGULATORY INFORMATION

EU EINECS/ELINCS List	215-185-5

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Skin corrosion/irritation-Cat. 1A; Skin corrosion/irritation-Cat. 1B; H314 - Causes severe skin burns and eye damage
 Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat. 3; H335 - May cause respiratory irritation

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information.
Revision date:	25-Oct-2016
Prepared by:	Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



COLGATE-PALMOLIVE Company
SAFETY DATA SHEET

NA

SOFTSOAP ANTIBACTERIAL LIQUID HAND SOAP

This industrial Safety Data Sheet provides health and safety information for occupational use only.

Version 1.0

SDS Number: 660000000608

Revision Date: 06/09/2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : SOFTSOAP ANTIBACTERIAL LIQUID HAND SOAP

Product code : 200000045435

: B02960040001

Manufacturer or supplier's details

Company : Colgate-Palmolive Co
300 Park Avenue
New York, NY 10022

Telephone : US: Consumer Affairs - 1-800-468-6502

Emergency telephone number : For emergencies involving spill, leak, fire, exposure or accident call CHEMTREC (24hr) at (800) 424-9300 or (703) 527-3887.

Medical Emergency (24HR): For MEDICAL EMERGENCIES involving this product call: (888) 489-3861

Recommended use of the chemical and restrictions on use

Recommended use : A formulated fragrance for consumer products.

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Physical state	liquid
Colour	colourless

GHS Classification

Skin irritation : Category 2

Eye irritation : Category 2A

GHS Label element

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.



COLGATE-PALMOLIVE Company
SAFETY DATA SHEET

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SOFTSOAP ANTIBACTERIAL LIQUID HAND SOAP

This industrial Safety Data Sheet provides health and safety information for occupational use only.

Version 1.0

SDS Number: 660000000608

Revision Date: 06/09/2015

Precautionary statements : **Prevention:**
 P264 Wash skin thoroughly after handling.
 P280 Wear eye protection/ face protection.
 P280 Wear protective gloves.
Response:
 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.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 P362 Take off contaminated clothing and wash before reuse.

Potential Health Effects

Inhalation : Overexposure may cause respiratory tract irritation.

Skin : Causes skin irritation. Prolonged contact may cause allergic dermatitis.

Eyes : Causes eye irritation on direct contact.

Ingestion : May be harmful if swallowed in large quantities.

Aggravated Medical Condition : None known.

Carcinogenicity:

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA No component 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 component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
CETRIMONIUM CHLORIDE	112-02-7	>= 1 - < 5



COLGATE-PALMOLIVE Company
SAFETY DATA SHEET

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SOFTSOAP ANTIBACTERIAL LIQUID HAND SOAP

This industrial Safety Data Sheet provides health and safety information for occupational use only.

Version 1.0

SDS Number: 660000000608

Revision Date: 06/09/2015

GLYCERIN	56-81-5	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

If inhaled	: Remove victim to fresh air. Get medical attention, if symptoms persist.
In case of skin contact	: Flush skin with large amounts of water. If irritation develops and persists, get medical attention.
In case of eye contact	: Flush eyes with water at least 15 minutes. Get medical attention if eye irritation develops or persists.
If swallowed	: Drink 8 ounces of clear water. Get medical attention.
Most important symptoms and effects, both acute and delayed	: Causes skin irritation. Causes serious eye irritation.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Hazardous combustion products	: No hazardous combustion products are known
Special protective equipment for firefighters	: Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protection recommended in Section 8 of the SDS.
Methods and materials for containment and cleaning up	: Cover with inert, absorbent material and remove to disposal container. Spill area may be slippery. Flush with plenty of water.

SECTION 7. HANDLING AND STORAGE

Conditions for safe storage	: Store at controlled room temperature at 20-25°C (68-77°F).

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parameter	Basis



COLGATE-PALMOLIVE Company
SAFETY DATA SHEET

NA

SOFTSOAP ANTIBACTERIAL LIQUID HAND SOAP

This industrial Safety Data Sheet provides health and safety information for occupational use only.

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		(Form of exposure)	ters / Permissible concentration	
GLYCERIN	56-81-5	TWA (mist, respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (mist, total dust)	15 mg/m ³	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m ³	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m ³	OSHA P0

Engineering measures : In an industrial work environment, no special precautions or control measures are required.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Protective measures : In an industrial work environment, if a splash is likely, chemical goggles may be needed. Prolonged skin contact may require protective gloves. For consumer use, no unusual precautions are necessary.

Hygiene measures : In an industrial work environment, avoid eye and prolonged skin contact.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless

pH : 8.6

Flash point : > 200 °F

Density : > 0.0000 g/cm³

SECTION 10. STABILITY AND REACTIVITY

Possibility of hazardous reactions : Hazardous polymerisation does not occur.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : None known.



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SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components:

CETRIMONIUM CHLORIDE:

Acute oral toxicity : LD50 (Rat): 450 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit): 429 mg/kg
Method: OECD Test Guideline 402

GLYCERIN:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
Method: No information available.

Skin corrosion/irritation

Causes skin irritation.

Components:

CETRIMONIUM CHLORIDE:

Result: Corrosive after 1 to 4 hours of exposure

GLYCERIN:

Result: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

CETRIMONIUM CHLORIDE:

Result: Irreversible effects on the eye

GLYCERIN:

Remarks: No data available



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Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

CETRIMONIUM CHLORIDE:

Exposure routes: Inhalation

Result: Does not cause respiratory sensitisation.

Exposure routes: Dermal

Result: Does not cause skin sensitisation.

GLYCERIN:

Exposure routes: Inhalation

Remarks: No data available

Exposure routes: Dermal

Result: Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Further information

Product:

Remarks: This product has not been tested as a whole. However, this formula was reviewed by expert toxicologists in the Product Safety Assurance Department of Colgate-Palmolive and is determined to be safe for its intended use. This review has taken into consideration available safety-related information including information on individual ingredients, similar formulas and potential ingredient interactions. This review is a component of the hazard determination used to prepare the statements in Section 3 of the SDS.

SECTION 12. ECOLOGICAL INFORMATION

The product has not been tested as a whole for environmental toxicity. However, environmental information on the ingredients in this product have been reviewed by the Environmental, Health and Safety group of Colgate-Palmolive and determined to have an acceptable environmental profile. This evaluation is based on available information on individual ingredients, interactions of ingredients, and similar ingredients. Biodegradability claims are supported by data on ingredients (i.e., surfactants are biodegradable) or testing conducted on the final product (i.e., This product is biodegradable).



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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Any disposal practice must be in compliance with local, state and federal laws and regulations (contact local or state environment agency for specific rules). Do not dump in sewers, any body of water or on the ground.

SECTION 14. TRANSPORT INFORMATION

DOT : Not regulated.

TDG : Not regulated.

IATA : Not regulated.

IMDG : Not regulated.

ADR :

International Regulation

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : Toxic by ingestion, Moderate skin irritant, Severe eye irritant

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
HYDROGEN PEROXIDE	7722-84-1	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 311/312 Hazards : Acute Health Hazard



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SARA 302

: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

GLYCERIN	56-81-5

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

GLYCERIN	56-81-5
HYDROGEN PEROXIDE	7722-84-1

Pennsylvania Right To Know

WATER	Water
GLYCERIN	56-81-5

New Jersey Right To Know

WATER	Water
CETRIMONIUM CHLORIDE	112-02-7
GLYCERIN	56-81-5
LAURAMIDOPROPYLDIMETHYLAMINE	61792-31-2
OXIDE	

California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.



NA

SOFTSOAP ANTIBACTERIAL LIQUID HAND SOAP

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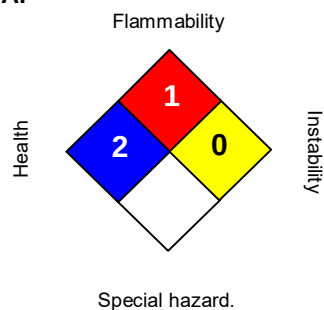
SDS Number: 660000000608

Revision Date: 06/09/2015

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Disclaimer: The information on this sheet is limited to the material identified and is believed by the Colgate-Palmolive Company to be correct based on its knowledge and information as of the date noted. Colgate makes no representation, guarantee or warranty, expressed or implied, as to the accuracy, reliability or completeness of the information and assumes no responsibility for injury, damage or loss resulting from the use of the material.



SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Hydrocortisone Sodium Succinate for Injection (Act-O-Vial)

Trade Name: Solu-Cortef
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
 235 East 42nd Street
 New York, New York 10017
 1-800-879-3477

Pfizer Ltd
 Ramsgate Road
 Sandwich, Kent
 CT13 9NJ
 United Kingdom
 +00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 P281 - Use personal protective equipment as required
 P308 + P313 - IF exposed or concerned: Get medical attention/advice
 P405 - Store locked up
 P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Material Name: Hydrocortisone Sodium Succinate for Injection (Act-O-Vial)
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**Other Hazards**

Australian Hazard Classification (NOHSC):

No data available

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Hydrocortisone Sodium Succinate	125-04-2	204-725-5	Repr.Cat.3;R63	Repr. 2 (H361d)	< 86
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	<14

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES**Description of First Aid Measures****Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

Hydrocortisone Sodium Succinate

Pfizer OEL TWA-8 Hr: 100µg/m³, Skin

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Analytical Method:

Analytical method available for hydrocortisone. Contact Pfizer Inc for further information.

Exposure Controls**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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Material Name: Hydrocortisone Sodium Succinate for
Injection (Act-O-Vial)
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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder plus sterile diluent	Color:	White to off-white
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
Solubility:	Soluble: Water		
pH:	7-8 (solution)		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Sodium phosphate, dibasic			
No data available			
Sodium phosphate, monobasic			
No data available			
Sodium hydroxide			
No data available			
Hydrocortisone Sodium Succinate			
No data available			
Benzyl Alcohol			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):	No data available		
Flammability (Solids):	No data available		
Flash Point (Liquid) (°C):	No data available		
Upper Explosive Limits (Liquid) (% by Vol.):	No data available		
Lower Explosive Limits (Liquid) (% by Vol.):	No data available		

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under recommended storage conditions. Solutions are unstable after 4 hours.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye, skin and respiratory tract irritation (based on components) . May be absorbed through the skin in harmful amounts. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Effects on vision have been seen during clinical use. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension). Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Hydrocortisone Sodium Succinate

Rat Oral LD 50 5000 mg/kg

Mouse Oral LD 50 5000mg/kg

Rat Subcutaneous LD 50 449mg/kg

Mouse Subcutaneous LD 50 >500mg/kg

Rat Intraperitoneal LD 50 150mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg

Rat Para-periosteal LD50 53mg/kg

Rat Inhalation LC50 >4.178mg/L

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Hydrocortisone Sodium Succinate

Eye Irritation Rabbit Minimal

Benzyl Alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Hydrocortisone Sodium Succinate

7 Day(s) Mouse Oral 140 mg/kg/day LOAEL Thymus

4 Day(s) Mouse Subcutaneous 100 mg/kg/day LOAEL Liver

SAFETY DATA SHEET

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11. TOXICOLOGICAL INFORMATION

11 Day(s)	Mouse	Subcutaneous	62 mg/kg/day	LOAEL	Endocrine system
2 Week(s)	Mouse	Subcutaneous	560 mg/kg/day	LOAEL	Liver, Bone Marrow
85 Day(s)	Rat	Subcutaneous	175 mg/kg/day	LOAEL	Adrenal gland

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**Hydrocortisone Sodium Succinate**

Reproductive & Fertility-Females	Rat	Oral	210 mg/kg/day	LOAEL	Maternal toxicity
Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	LOAEL	Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Hydrocortisone Sodium Succinate**

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo In Vitro Direct DNA Damage Rat , Mouse Positive
In Vivo In Vitro Chromosome Aberration Rat , Mouse Positive
 Cytogenetics Mouse Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: ClassificationsWHMIS hazard class:

Class D, Division 2, Subdivision A

**Hydrocortisone Sodium Succinate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	204-725-5

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-449-2

Sodium phosphate, dibasic

SAFETY DATA SHEET

Material Name: Hydrocortisone Sodium Succinate for
Injection (Act-O-Vial)
Revision date: 16-May-2014

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

16. OTHER INFORMATION**Text of R phrases and GHS Classification abbreviations mentioned in Section 3**

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Toxic to Reproduction: Category 3
C - Corrosive
Xn - Harmful

R35 - Causes severe burns.
R63 - Possible risk of harm to the unborn child.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.
Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and
Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 -
Stability and Reactivity. Updated Section 13 - Disposal Considerations. Updated Section 11 -
Toxicology Information. Updated Section 16 - Other Information.

Revision date: 16-May-2014

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Trade Name: Solu-Medrol; Solu-Medrone; Solu-Moderin
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
 235 East 42nd Street
 New York, New York 10017
 1-800-879-3477

Pfizer Ltd
 Ramsgate Road
 Sandwich, Kent
 CT13 9NJ
 United Kingdom
 +00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
 Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements: H373 - May cause damage to organs through prolonged or repeated exposure H360D - May damage the unborn child
 May form combustible dust concentrations in air

Precautionary Statements: P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P281 - Use personal protective equipment as required
 P308 + P313 - IF exposed or concerned: Get medical attention/advice
 P314 - Get medical attention/advice if you feel unwell
 P405 - Store locked up
 P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0
Methylprednisolone Sodium Succinate	2375-03-3	219-156-8	Repr. 1A (H360D) STOT RE 2 (H373)	67-87

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES**Description of First Aid Measures****Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE**Precautions for Safe Handling**

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control Parameters**

METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Methylprednisolone Sodium Succinate

Pfizer OEL TWA-8 Hr: 4 µg/m³, Skin

Exposure Controls**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES**Physical State:**

Powder

Color:

White

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

Soluble: Alcohols

Water Solubility:

No data available

Solubility:

Soluble: Water

pH:

No data available.

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)**Sodium phosphate, dibasic**

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES**Sodium phosphate, monobasic**

No data available

Lactose

No data available

Methylprednisolone Sodium Succinate

No data available

Methylprednisolone

Predicted 7.4 Log D 1.99

Benzyl Alcohol

No data available

Decomposition Temperature (°C): No data available.**Evaporation Rate (Gram/s):** No data available**Vapor Pressure (kPa):** No data available**Vapor Density (g/ml):** No data available**Relative Density:** No data available**Viscosity:** No data available**Flammability:****Autoignition Temperature (Solid) (°C):** No data available**Flammability (Solids):** No data available**Flash Point (Liquid) (°C):** No data available**Upper Explosive Limits (Liquid) (% by Vol.):** No data available**Lower Explosive Limits (Liquid) (% by Vol.):** No data available**10. STABILITY AND REACTIVITY****Reactivity:** No data available**Chemical Stability:** Stable under normal conditions of use.**Possibility of Hazardous Reactions****Oxidizing Properties:** No data available**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers**Hazardous Decomposition Products:** No data available**11. TOXICOLOGICAL INFORMATION****Information on Toxicological Effects****General Information:**

The information included in this section describes the potential hazards of various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.

Short Term:

May cause eye irritation (based on components) . May be harmful if absorbed through the skin.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.

Known Clinical Effects:

Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use has resulted in hormonal alterations. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

Acute Toxicity: (Species, Route, End Point, Dose)

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11. TOXICOLOGICAL INFORMATION

Methylprednisolone Sodium Succinate

Rat Oral LD 50 > 5000 mg/kg
 Rat Para-periosteal LD 50 718mg/kg
 Mouse Intravenous LD 50 953mg/kg
 Rat Intraperitoneal LD 50 512mg/kg
 Mouse Intraperitoneal LD 50 902mg/kg

Methylprednisolone

Rat Oral LD 50 > 2000 mg/kg
 Mouse Oral LD 50 450mg/kg
 Rat Intraperitoneal LD 50 1000mg/kg
 Mouse Intraperitoneal LD 50 1409mg/kg
 Rat Subcutaneous LD 50 >3000mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
 Rat Para-periosteal LD50 53mg/kg
 Rat Inhalation LC50 >4.178mg/L

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Methylprednisolone

Skin Irritation Rabbit No effect
 Eye Irritation Rabbit No effect
 Skin Sensitization - GPMT Guinea Pig No effect

Benzyl Alcohol

Eye Irritation Rabbit Severe
 Skin Irritation Rabbit Minimal
 Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Methylprednisolone

42 Day(s) Dog Oral 167 µg/kg/day LOAEL Adrenal gland
 6 Week(s) Rat Subcutaneous 500 µg/kg/day LOAEL None identified
 14 Week(s) Rat Subcutaneous 0.4 µg/kg/day NOAEL Blood forming organs, Adrenal gland
 52 Week(s) Rat Subcutaneous 4 µg/kg/day NOAEL Blood forming organs Adrenal gland

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Methylprednisolone Sodium Succinate

Reproductive & Fertility Rat Subcutaneous 40 mg/kg/day LOAEL Fetotoxicity
 Embryo / Fetal Development Rat Subcutaneous 40 mg/kg/day LOAEL Teratogenic

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11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility	Rat	Subcutaneous	0.004 mg/kg/day	NOAEL	Paternal toxicity
Reproductive & Fertility	Rat	Subcutaneous	0.02 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	1.0 mg/kg/day	LOAEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Intramuscular	330 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.1 mg/kg/day	LOAEL	Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Methylprednisolone Sodium Succinate**

Direct DNA Interaction	Not applicable	Negative
<i>In Vitro</i> Cytogenetics	Not applicable	Negative

Methylprednisolone

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
Direct DNA Interaction		Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION**Environmental Overview:**

Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)****Benzyl Alcohol**

<i>Pimephales promelas</i> (Fathead Minnow)	EPA	LC50	96 Hours	460 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	230 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EC50	72 Hours	500 mg/L

Benzyl Alcohol

<i>Daphnia magna</i> (Water Flea)	OECD	21 Day(s)	EC50	66 mg/L	Reproduction

Persistence and Degradability:**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)****Benzyl Alcohol**

OECD	Activated sludge	Ready	92% After	14 Day(s)	Ready

Bio-accumulative Potential:**Partition Coefficient: (Method, pH, Endpoint, Value)****Methylprednisolone**

Predicted	7.4	Log D	1.99

Mobility in Soil:

No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-449-2

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

Lactose

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2

Methylprednisolone Sodium Succinate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	219-156-8

16. OTHER INFORMATION**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 27-Oct-2016

Prepared by: Product Stewardship Hazard Communication
 Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



STELARA

Version 1.3	Revision Date: 2016-07-19	SDS Number: 100000009229	Date of last issue: 2016-07-09 Date of first issue: 2016-06-24

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

1.1 Product identifier

Trade name	: STELARA
Substance name	: STELARA 45mg, 90mg vial/syringe, 5mg/mL FVP (IV)(26mL fill volume in 30mL vial -130mg in vial) ustekinumab CNTO 1275

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

Use of the Substance/Mixture	: Finished Pharmaceutical Product, Large Molecule Pharmaceutical intended for medical use, Monoclonal antibody, Pharmacotherapeutic group: Immunosuppressive agents, This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component. A safety data sheet is not required for this product under Article 31 of REACH. This SDS has been created on a voluntary basis (to pass on relevant information required under Article 32). Since an SDS is not required, this document may not contain all of the information that is required for substance and mixture SDS's under REACH.

1.3 Details of the supplier of the safety data sheet

Company	: Janssen Pharmaceutica NV Turnhoutseweg 30 2340 Beerse Belgium
Telephone	: +3214602111
Telefax	: +3214602841
E-mail address Responsible/issuing person	: SDSJanssen@its.jnj.com

1.4 Emergency telephone number

CHEMTREC GB: +(44)-870-8200418
CHEMTREC International: +1 703-527-3887

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Supplemental Hazard Statements : Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible personse. This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
WEL substance :			
Ustekinumab	815610-63-0		< 10

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : If breathed in, move person into fresh air.

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Consult a physician.

- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with plenty of water.
If symptoms persist, call a physician.
Wash contaminated clothing before re-use.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is con-
scious).
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.
Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-
cumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire- : No information available.
fighting

5.3 Advice for firefighters

- Special protective equipment : In the event of fire, wear self-contained breathing apparatus.
for firefighters

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : In the event of an accidental release the emergency response
team must respond based on a risk assessment and use per-

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sonal protective equipment as appropriate.
Avoid direct contact with broken glass, plastic and other sharps.
Avoid splashes and spray formation.
Evacuate personnel to safe areas.
Avoid direct contact and significant aerosol exposure.
Do not break, crush or spill this Finished Pharmaceutical Product.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Small spills: Gently cover the spill with an absorbent towel or pad.
Wet absorbent pad with 10% bleach solution. Allow 30 minutes contact time.
Large spills: Allow the dust/aerosol to settle for 30 minutes or use appropriate respiratory protection.
Dam up.
Soak up with inert absorbent material.
Add bleach (5.25% sodium hypochlorite) solution to a final liquid concentration of 10% (1 part bleach, mixed with 9 parts liquid) to absorbent materials. Allow 30 minute contact time.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Clean up with a 10% bleach (5.25% sodium hypochlorite) solution, 1 part bleach, mixed with 9 parts water is recommended for cleaning of surfaces and equipment.
Clean spill location and adjacent surfaces thoroughly with ethanol or water with detergent.
Special consideration may need to be evaluated based on specific hazards.

6.4 Reference to other sections

For disposal information, see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
Avoid splashes.
Avoid formation of aerosol.
To avoid thermal decomposition, do not overheat.
Avoid inhalation, ingestion and contact with skin and eyes.
Use personal protective equipment as required.

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Advice on protection against fire and explosion : No data available

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove gloves and wash hands when work with material is completed. Do not reuse gloves. In some cases, wearing two pairs of gloves may be appropriate. Contaminated work clothing should not be allowed out of the workplace.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition.

Recommended storage temperature : 2 - 8 °C

Other data : Keep refrigerated. Do not freeze. Protect against light.

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ustekinumab	815610-63-0	PBOEL-HHC	2	J&J OEL/PBOEL HHC
Further information	J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2.			
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	TWA	10 mg/m ³	GB EH40
		STEL	20 mg/m ³	GB EH40

8.2 Exposure controls

Personal protective equipment

Eye protection : No special precautions required.

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Hand protection Remarks	: No special precautions required.
Skin and body protection	: No special precautions required.
Respiratory protection	: No personal respiratory protective equipment normally required. Engineering controls should always be the primary method of controlling exposures. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
Protective measures	: The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: Prefilled syringe, Aqueous solution, Vial
Colour	: colourless, light yellow
pH	: ca. 6
Solubility(ies) Water solubility	: soluble

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

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Conditions to avoid : To avoid thermal decomposition, do not overheat.
Exposure to light.

10.5 Incompatible materials

Materials to avoid : None known.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Respiratory or skin sensitisation

Components:

Ustekinumab:

Remarks: Large protein biotherapeutics in the dry or reconstituted (solution in buffer) forms are not expected to elicit skin corrosion/irritation, skin sensitization, or cause damage to/irritate the eyes.

Assessment: Single-dose acute toxicity studies were not performed. This product is a large protein biotherapeutic intended for injection. It is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

Germ cell mutagenicity

Components:

Ustekinumab:

Germ cell mutagenicity- Assessment : Routine genotoxicity studies are not applicable to biotherapeutics as large proteins cannot diffuse into cells and interact with DNA or chromosomal material.

Carcinogenicity

No data available

Reproductive toxicity

Components:

Ustekinumab:

Effects on fertility : Species: Mouse
Sex: male

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



STELARA

Version 1.3	Revision Date: 2016-07-19	SDS Number: 100000009229	Date of last issue: 2016-07-09 Date of first issue: 2016-06-24

Dose: 45 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal

Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Species: Mouse
Sex: female
Dose: 50 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal

Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Effects on foetal development : Species: Monkey
Dose: 45 mg/kg
Number of exposures: weekly
Remarks: Did not show teratogenic effects in animal experiments.
Species: Monkey
Dose: 45 mg/kg
Number of exposures: twice weekly
Remarks: Did not show teratogenic effects in animal experiments.

Reproductive toxicity - Assessment : As maternal systemic exposure from handling is expected to be negligible and placental transfer of monoclonal antibodies in humans is very low during the period of organogenesis (1st trimester), embryo/fetal harm from worker exposure is considered unlikely.

STOT - single exposure

Product:

Remarks: Even though this does not meet GHS classification, inhalation of aerosol/dust from an acute exposure or significant overexposure may cause autoantibody formation or allergies.

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

Ustekinumab:

Species: Monkey
45 mg/kg
Application Route: intravenous injection
Exposure time: 1 month
Number of exposures: weekly

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



STELARA

Version 1.3	Revision Date: 2016-07-19	SDS Number: 100000009229	Date of last issue: 2016-07-09 Date of first issue: 2016-06-24

Remarks: No adverse effect has been observed in chronic toxicity tests.

Species: Monkey

45 mg/kg

Application Route: Subcutaneous; injection made in the back or neck of animal

Exposure time: 6 months

Number of exposures: twice weekly

Remarks: No adverse effect has been observed in chronic toxicity tests.

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

Ustekinumab:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

12.2 Persistence and degradability

Components:

Ustekinumab:

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Components:

Ustekinumab:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

Product:

Additional ecological information : Remarks: No data available

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



STELARA

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.3	2016-07-19	100000009229	Date of first issue: 2016-06-24

Components:

Ustekinumab:

Additional ecological information : Remarks: There is no data available for this product. Should not be released into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : In accordance with National, Federal, State and Local regulations.
Decontaminate all waste before disposal (steam sterilization, chemical disinfection and/or incineration).

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations : Restricted to professional users.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



STELARA

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.3	2016-07-19	100000009229	Date of first issue: 2016-06-24

According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
Biosafety Regulations and Guidelines:
World Health Organization, Laboratory biosafety manual. - 3rd ed., ISBN 92 4 154650 6 (LC/NLM classification: QY 25)
WHO/CDS/CSR/LYO/2004.11.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012-12-31
Numbers:	123456,78	as	123 456,78

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.

GB / EN



PRODUCTS NOT REQUIRING MATERIAL SAFETY DATA SHEETS

The Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (29CFR1910.1200) requires manufacturers to prepare material safety data sheets for chemical products which are considered "hazardous" according to the regulation. For a chemical or formulation to be hazardous, it must present either a physical hazard or health hazard. The list below identifies those Hospira products that do not meet OSHA's "hazardous" chemical classification. Material safety data sheets have not been prepared for the products listed below.

4 Trace Elements Injection	Dextrose Injection	Potassium Chloride in Dextrose Injection
Acetic Acid Irrigation	Glycine Irrigation	Potassium Chloride in Lactated Ringer's and Dextrose Injection
Aminosyn® (An Amino Acid Injection)	Hetastarch in Sodium Chloride Injection	Potassium Chloride in Sodium Chloride Injection
Aminosyn® in Dextrose Injection	Hextend® - 6% Hetastarch in Lactated Electrolyte Injection	Potassium Chloride Injection
Ascorbic Acid Injection	Ionosol® and Dextrose Injection	Potassium Phosphates Injection
Balanced Salt Solution	Lactated Ringer's Injection	Ringer's Injection
Calcium Acetate Injection	Lactated Ringer's Irrigation	Ringer's Irrigation
Calcium Gluconate Injection	Liposyn® (I.V. Fat Emulsion)	Sodium Acetate Injection
Cardioplegic Solution (Plegisol®)	LMD in Dextrose Injection	Sodium Bicarbonate Injection
Chromic Chloride Injection	LMD in Sodium Chloride Injection	Sodium Chloride Injection
Cupric Chloride Injection	Manganese Chloride Injection	Sodium Chloride Irrigation
Dextran in Dextrose Injection	Mannitol Injection	Sodium Lactate Injection
Dextran in Sodium Chloride Injection	Medical Devices	Sodium Phosphates Injection
Dextrose and Lactated Ringer's Injection	Normosol® Injection	Sorbitol-Mannitol Irrigation
Dextrose and Ringer's Injection	Physiosol® Irrigation	Sterile Water for Injection
Dextrose and Sodium Chloride Injection	Potassium Acetate Injection	Sterile Water for Irrigation
	Potassium Chloride in Dextrose and Sodium Chloride Injection	Theophylline in Dextrose Injection
		Zinc Chloride Injection

Thomas D. Straits MPH, CIH
MSDS Coordinator

Hospira, Inc.

275 North Field Drive

Dept. 67C, Bldg. AP4A

Lake Forest, IL 60045

www.hospira.com

June 2004



SAFETY DATA SHEET



1. IDENTIFICATION

Product Name: Super Sani-Cloth Germicidal Wipe

(SDS 0020-00)

Date of Preparation: October 27, 2015

Recommended use of the chemical and restrictions on use:

Recommended use: Use as a disinfectant on hard, non-porous surfaces. Read and understand the entire label before using. Use only according to label directions. It is a violation of Federal law to use this product in a manner inconsistent to label directions.

Restrictions on use: For Professional and Hospital Use.

Manufacturer/Supplier: Nice-Pak/PDI, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962-1376

Phone Number: 1-845-365-1700

Emergency Phone Number: PERS: 1-800-633-8253 (Domestic/Canada)
1-801-629-0667 (International)

2. HAZARD(S) IDENTIFICATION

This product is a colorless to slightly yellow liquid with a alcohol odor impregnated on a wipe. There is a small amount of liquid on the wipe and very small amount of free liquid in the packages.

GHS Classification:

Physical	Health	Environmental
Flammable Solids Category 1	Eye Irritant Category 2A	Not Classified

Label Elements:

Danger!



Hazard Statements:

Flammable solid

Causes serious eye irritation.

Precautionary Statements:

Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

Wash thoroughly after handling.

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 attention.

In case of fire: Use water, water fog, dry chemical or carbon dioxide to extinguish.

Super Sani-Cloth Germicidal Wipe
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Other Hazards: None known.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Isopropyl Alcohol	67-63-0	55%
Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	68391-01-5	0.25%
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	85409-23-0/ 68956-79-6	0.25%

4. FIRST-AID MEASURES

Description of First Aid Measures:

Eye: Flush eyes with large quantities of water for several minutes. Remove contact lenses if easy to do so. Continue rinsing. Get medical attention if irritation persists.

Skin: No first aid should be required. Wash skin with water. Get medical attention if irritation develops or persists.

Inhalation: Not a normal route of exposure. If symptoms develop move victim to fresh air. Get medical attention if symptoms develop.

Ingestion: Ingestion is unlikely for solid products. No first aid is required for small amounts transferred from hands to mouth.

Most Important Symptoms/Effects, Acute and Delayed: Direct contact may cause eye irritation.

Indication of Immediate Medical Attention and Special Treatment, If Necessary: None required under normal conditions of use.

5. FIRE-FIGHTING MEASURES

Suitable (and Unsuitable) Extinguishing Media: Use water, water fog, dry chemical, or carbon dioxide.

Specific Hazards Arising From the Chemical: This product is a flammable solid and will burn under fire conditions. Combustion may produce oxides of carbon, ammonia, and chloride compounds.

Special Protective Equipment and Precautions for Fire-Fighters: Wear an approved, positive pressure, self-contained breathing apparatus and full protective clothing. Cool fire exposed containers with water. Contain runoff.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Use non-sparking tools and equipment. Avoid contact with eyes and skin. Wear appropriate protective clothing as described in Section 8.

Environmental Hazards: Avoid releases to the environment. Report spill as required by local and federal regulations.

Methods and Materials for Containment and Cleaning Up: Do not reuse towelette. Pick up wipe and place in an appropriate container for infectious waste disposal. Do not flush in toilet.

7. HANDLING AND STORAGE

Precautions for Safe Handling: None required for normal use. Avoid contact with eyes and skin. Avoid breathing vapors. Refer product label for additional information on use and handling.

Nonrefillable container. Do not reuse or refill this container. Dispose in accordance with all local, state and federal regulations.

Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry location away from incompatible materials. Do not store near heat or open flame. Do not contaminate water, food or feed by storage or disposal. For containers: Protect container from physical damage. When not in use keep center cap of lid closed to prevent moisture loss.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

Isopropyl Alcohol	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL
Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	None Established
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	None Established

Appropriate Engineering Controls: General ventilation is adequate under normal conditions of use. Refer product label for additional information.

Individual Protection Measures, Such As Personal Protective Equipment:

Respiratory Protection: None required for normal use. In case of insufficient ventilation, wear suitable respiratory equipment. Refer product label for additional information.

Skin Protection: Avoid contact with skin.

Eye Protection: Avoid contact with eyes.

Other: None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Colorless to slightly yellow liquid saturated on a wipe	Flammable limits: LEL: 2.5% (Isopropyl Alcohol) UEL: 12% (Isopropyl Alcohol)
Odor: Alcohol odor	Vapor pressure: Not available
Odor Threshold: Not applicable	Vapor density: Not available
pH: 5.75-8.50 (Saturant)	Relative density: 0.892
Melting point/freezing point: -87.9°C (-126.22°F)	Solubility(ies): Soluble in water (Saturant)

Super Sani-Cloth Germicidal Wipe
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(Isopropyl Alcohol)	
Boiling point/range: 82.3°C (180.14°F) (Isopropyl Alcohol)	Partition coefficient (n-octanol/water): Not available
Flash point: 23.9°C (75.0°F)	Auto-ignition temperature: Not available
Evaporation rate: Not available	Decomposition temperature: Not available
Flammability (solid, gas): Flammable solid	

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use. This product may react in contact with incompatible materials.

Chemical Stability: Stable under normal storage and handling conditions.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions To Avoid: Keep away from heat, sparks, and open flames.

Incompatible Materials: Avoid contact with strong oxidizing agents, strong acids, isocyanates, and chlorine. Do not use on natural marble, windows, unpainted wood or brass, clear plastic or colored grout.

Hazardous Decomposition Products: Thermal decomposition may produce oxides of carbon, ammonia, and chloride compounds.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eye: This product is expected to cause moderate irritation to eyes based on test data from the OPPTS 870.2400 Acute Eye Irritation Study which resulted in Toxicity Category II.

Skin: No adverse effects are expected. This product is non-irritating based on test data from the OPPTS 870.2500 Acute Skin irritation study.

Inhalation: Inhalation of high concentrations of vapors may cause upper respiratory tract irritation, headache and dizziness.

Ingestion: Ingestion is unlikely for solid products. This product contains only a small amount of liquid. No adverse effects are expected.

Chronic Effects: None known.

Carcinogenicity: None of the components of this product are listed as a carcinogen or suspected carcinogen by OSHA, IARC, and NTP.

Reproductive Effects: Reproductive harm is not expected from this product.

Mutagenic Effects: Not expected to cause mutagenic activity.

Acute Toxicity:

No toxicity data available for the mixture. The following toxicity data is for the individual components:

Isopropyl Alcohol: Oral rat LD50: 4396 mg/kg, Dermal rabbit LD50: 12800 mg/kg, Inhalation rat LC50: 16970 mg/L/4hr

Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides: Oral rat LD50: 240 mg/kg, Dermal rat LD50: 1420-2000 mg/kg

Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride: Oral rat LD50: 250 mg/kg

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12. ECOLOGICAL INFORMATION

Ecotoxicity: No data available for this mixture. The following data is for the individual components:

Isopropyl Alcohol: 96 hr LC50 Bluegill (*Lepomis macrochirus*): >1400 mg/L, 48 hr EC50 Daphnia: 13299 mg/L, 72 hr IC50 Algae: 1000 mg/L

Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides and Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride: 96 hr LC50 Fish: 0.86 ppm, 48 hr EC50 Daphnia: 0.0058-0.016 mg/L

This product is classified as very toxic to the aquatic environment. Releases to the environment should be avoided.

Persistence and Degradability: No data available

Bioaccumulative Potential: No data available

Mobility in Soil: No data available

Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Dispenser or Container Disposal: Nonrefillable container. Do not reuse or refill this container. Dispose in accordance with all local, state and federal regulations.

Empty containers or liners may retain some product residues. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. This material and its container must be disposed of in a safe manner. Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
US DOT	UN3175	Solids containing flammable liquid, n.o.s. (Isopropyl Alcohol)	4.1	II	None
IMDG	UN3175	Solids containing flammable liquid, n.o.s. (Isopropyl Alcohol)	4.1	II	Yes
IATA	UN3175	Solids containing flammable liquid, n.o.s. (Isopropyl Alcohol)	4.1	II	None

Special precautions: None known

15. REGULATORY INFORMATION**Safety, Health, and Environmental Regulations Specific for the Product In Question:**

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.

FIFRA Labeling:**Keep Out Of Reach of Children****WARNING****PRECAUTIONARY STATEMENTS****Hazards to Humans & Domestic Animals**

Warning: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using restroom. Remove and wash contaminated clothing before reuse.

Physical or chemical hazard: Combustible. Do not use or store near heat or open flame. Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

CERCLA 103 Reportable Quantity: This product is not subject to reporting under CERCLA. Some states have more stringent reporting requirements. Report all spills in accordance with local, state, and federal regulations.

SARA TITLE III:

Hazard Category for Section 311/312: Acute Health, Fire Hazard

Section 313 Toxic Chemicals: This product contains the following chemicals subject to SARA Title III Section 313 Reporting requirements: None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a EPA Registered product #9480-4. However, all of the ingredients of this product are listed on the TSCA inventory.

STATE REGULATIONS:

California Proposition 65: This product does not contain a substance known in the State of California to cause cancer and/or reproductive harm.

CANADIAN REGULATIONS

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL).

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16. OTHER INFORMATION**HMIS Ratings:** Health – 2

Flammability – 3

Physical Hazard - 0

NFPA Ratings: Health – 2

Flammability – 3

Instability – 0

SDS Revision History: Revision 2. Formatting changed as SDS has been completed by a different vendor. Based on further test data, the following changes have been made: Eye hazard category changed to 2A. Eye hazard statement downgraded. Eye irritation terminology downgraded for precautionary statement and first aid. Precautions for safe handling downgraded. Potential health effects to eyes downgraded.

Date of preparation: October 27, 2015**Date of last revision:** December 7, 2017



1. Product and Company Identification

PRODUCT NAME: SYNVISIC® (hylan G-F 20)

Substance name: Hylan G-F 20; Hylan polymer solution; Cross-linked hylan polymer

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 product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification: Not classified as a hazardous substance or mixture.

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, hylan G-F 20:

Signal Word: None required.

Hazard Statement(s): None required.

Symbol(s): None required.

Precautionary Statement(s):

- Prevention: None required.

- Response: None required.
- Storage: None required.
- Disposal: None required.

2.3 Hazards Not Otherwise Classified (HNOC)

None known.

3. Composition/Information on Ingredients

<u>Chemical name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
Formaldehyde cross-linked hyaluronan	Hylan A	507454-10-6	0.16 %
Divinyl sulfone cross-linked hyaluronan	Hylan B	872131-04-9	0.64 %
Water	Water for injection	7732-18-5	98.33 %
Sodium chloride	Sodium chloride	7647-14-5	0.85 %
Disodium hydrogen phosphate anhydrous	Sodium phosphate dibasic, anhydrous	7558-79-4	0.016 %
Sodium dihydrogen phosphate anhydrous	Sodium phosphate monobasic , anhydrous	7558-80-7	0.004 %

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 water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. 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.

4.2 Most important symptoms and effects, both acute and delayed

Not significantly absorbed orally or by inhalation. Reversible variable increases in white blood cells and platelet counts have been observed when administered by injection.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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 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

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Store at room temperature below 86°F (30°C). Protect from light. Do not freeze.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, hylan G-F 20: Not established.

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

Appearance: Clear, colorless liquid.

Odor: no data available.

Odor threshold: no data available.

pH: 7.2

Melting point/ 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: no data available.

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 nitrogen.

11. Toxicological Information

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: None identified.

Effects of short-term (acute) exposure: No data available.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD₅₀): No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: 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: No data available.

Not listed by NTP, and are not found to be potential carcinogens by IARC or OSHA.

Reproductive toxicity and teratogenicity: No data available.

Mutagenicity: No data available.

Aspiration hazard: No data available.

12. Ecological Information

12.1. Ecotoxicity

No data available.

12.2. Persistence and degradability

No data available.

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.

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

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

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.

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.

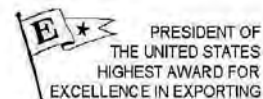
Abbreviations and Acronyms

AIHA: American Industrial Hygiene Association
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
WEEL: Workplace environmental exposure level

Date Prepared: November 16, 2016
Second version.



PHARMACEUTICAL INNOVATIONS, INC.



897 Frelinghuysen Avenue • Newark, New Jersey 07114-2195 • (973) 242-2900 • Fax: (973) 242-0578

Material Safety Data Sheet

T-SPRAY TRANSDUCER DETERGENT DISINFECTANT SPRAY

Section 1 – Material Identification

Product: T-Spray Transducer Detergent Disinfectant Spray
Date Prepared: 01/01/2011

Manufacturer: Pharmaceutical Innovations, Inc.
Telephone: 973-242-2900

Section 2 – Hazardous Ingredients

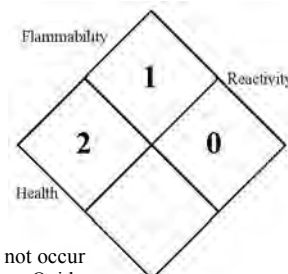
	OSHA PEL	ACGIH TLV
N-ALKYL (C12-18)-N, N-DIMETHYL-N-BENZYL AMMONIUM CHLORIDE (CAS 68391-01-5)	NL	NL
ALKYL DIMETHYL ETHYL BENZYL AMMONIUM CHLORIDE (C12-14) (CAS 68956-79-6)	NL	NL

Section 3 – Physical/Chemical Characteristics

Boiling Point:	Approx. 212F	Evaporation Rate:	ND
Solubility in Water:	Complete	Density:	1.01 g/cc
Vapor Density:	>1	Vapor Pressure (mm Hg):	ND
Appearance & Odor:	Blue green, perfumed, clear liquid		

Section 4 – Fire and Explosion Hazard Data

Flash Point:	ND	Lower Exposure Limit:	ND
Extinguishing Media:	All Types	Upper Exposure Limit:	ND
Flammable Limits:	ND		
Unusual Fire and Explosion Hazards:	None		
Special Fire fighting procedures:	Use self-contained breathing apparatus for maximum respiratory protection.		



Section 5 – Reactivity Data

Stability:	Stable	Hazardous Polymerization:	Will not occur
Incompatibility:	Strong oxidizing agents	Hazardous Decomposition Products:	Nitrous Oxides Ammonical vapors

Section 6 – Health Hazard Data

Route of Entry	Effect	Carcinogenicity	
Health Hazards:	Contact with eyes causes irritation. Prolonged or repeated contact with skin may cause irritation. Vapors or mist may irritate respiratory passage.	NTP IARC OSHA	None None None
			This product is not considered a carcinogen by OSHA, NTP, or IARC

Signs and Symptoms of Exposure: ND Medical Conditions Aggravated: N/A

Emergency and First Aid Procedures:

Eye Contact:	Flush eyes immediately with plenty of water for at least 15 minutes. Call a physician.
Skin Contact:	Wash off skin and remove contaminated clothing. Wash contaminated clothing before reuse.
Inhalation:	If vapors or mist cause distress, remove to fresh air.
Indigestion:	If swallowed, consult a physician immediately. Probable mucosal damage may contraindicate the use of gastric lavage. Drink egg whites or gelatin solution, or if these are not available, drink large quantities of water.

Section 7 – Precautions for Safe Handling and Use

Accidental Release:	Contain spills and leaks to prevent discharge to the environment. Ventilate immediately.
Small Spills:	Soak up with absorbent, shovel into waste containers. Flush area with water.
Large Spills:	Recover spilled material for disposal.
Waste Disposal Method:	Material collected with absorbent may be disposed in a permitted landfill in accordance with federal, state, and local regulations.
Precautions to Be Taken in Handling and Storing:	Avoid overheating or freezing.

Section 8 – Control Measures

Respiratory Protection:	NR	Ventilation:	NR
Protective Gloves:	NR	Local:	NR
Other Protective Measures:	N/A		
Work/Hygienic Practices:	Normal	Eye Protection:	NR

This Material Safety Data Sheet (MSDS) has been prepared in compliance with Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200. Pharmaceutical Innovations believes this information to be reliable and up to date as of the date of this form, but makes no warrantee that it is.



SAFETY DATA SHEET

1. Identification

Product identifier	Taltz®
Other means of identification	
Item Code	PS1445, PS7724, 520047, 517421, ZD1445, ZD7724, PS1439, CT9557
Synonyms	LY2439821 formulation
Recommended use	Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company name	Eli Lilly and Company
Address	Lilly Corporate Center Indianapolis, IN 46285 United States
Telephone	Phone: +1-317-276-2000
E-mail	lilly_msds@lilly.com
Emergency phone number	CHEMTREC: +1-800-424-9300

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	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
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	%
Ixekizumab			12

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation	Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

This substance is a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, this substance/preparation is considered unlikely to produce health effects through relevant routes of occupational exposures.

5. Fire-fighting measures**Suitable extinguishing media**

Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

Not available.

Specific hazards arising from the chemical

Not applicable.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

General fire hazards

This product is an aqueous mixture which will not burn.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Avoid inhalation of mists or aerosols.

Methods and materials for containment and cleaning up

Prevent runoff from entering drains, sewers, or streams. Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum. See Section 8 of the SDS for Personal Protective Equipment.

Environmental precautions

No specific precautions.

7. Handling and storage**Precautions for safe handling**

Not available.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection**Occupational exposure limits****Lilly (LEG) Components****Type****Value**

Ixekizumab

TWA (12hrs)

250 ug/m3

TWA (8hrs)

380 ug/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Health Based Excursion Limit: Maintain Full Shift TWA

Appropriate engineering controls

Contained handling practices preferred. If open handling is necessary, use control measures (i.e. ventilated enclosure, local exhaust ventilation) to maintain airborne levels below the occupational exposure level (OEL).

Individual protection measures, such as personal protective equipment**Eye/face protection**

Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.

Skin protection**Hand protection**

Chemical resistant gloves.

Other

While monoclonal antibodies are not anticipated to be readily absorbed through the skin, wear impervious gloves and body covering (i.e. lab coat) to minimize skin contact.

Respiratory protection

Not required under normal conditions for liquid handling activities. If handling powder forms, consider appropriate respiratory protection to maintain exposure levels below occupational exposure level (OEL).

Thermal hazards

Not available.

General hygiene considerations

Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.

This substance is a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, oral and dermal routes of exposure are not considered occupationally relevant and potential bioavailability through inhalation is minimal. (drug substance)

9. Physical and chemical properties**Appearance**

Material name: Taltz®

4743 Version #: 01 Issue date: 03-23-2016

SDS US

2 / 6

Physical state	Liquid.
Form	Liquid.
Color	Colorless.
Odor	Odorless
Odor threshold	Not available.
pH	5.7
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)	This product is an aqueous mixture which will not burn.
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)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None under normal conditions.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity	Due to lack of data the classification is not possible.
Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
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	This substance is a monoclonal antibody. It does not possess mutagenic potential. Mutagenicity testing has not been conducted. (drug substance)
Carcinogenicity	Not listed by IARC, NTP, ACGIH or OSHA. (drug substance) Due to lack of data the classification is not possible.
IARC Monographs. Overall Evaluation of Carcinogenicity	
Not available.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
US. National Toxicology Program (NTP) Report on Carcinogens	
Not available.	
Reproductive toxicity	Animal studies did not report any adverse effects on reproductive tissues, fertility ,or embryo/fetal development. (Weekly dosing) (drug substance) Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Except for injection site reactions, no treatment-related adverse effects have been reported in monkeys administered once-weekly subcutaneous doses for up to 39 weeks. (drug substance) Based on available data, the classification criteria are not met.
Aspiration hazard	Not applicable.
Further information	This substance is a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, oral and dermal routes of exposure are not considered occupationally relevant and potential bioavailability through inhalation is minimal. (drug substance)

12. Ecological information

12.1. Toxicity	Not expected to be harmful to aquatic organisms.
12.2. Persistence and degradability	Not available.
12.3. Bioaccumulative potential	Not available.
Partition coefficient n-octanol/water (log Kow)	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	Not available.
12.6. Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations.

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.

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 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

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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** 03-23-2016**Version #** 01

Lilly Lab Code Health: 0
 Fire: 0
 Reactivity: 0

List of abbreviations

LEG: Lilly Exposure Guideline
 TWA: Time Weighted Average

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company
Hazard Communication
+1-317-651-9533

Revision Information

Product and Company Identification: Product Codes

Physical and chemical properties: Flammability (solid, gas)

Toxicological information: Mutagenicity

Other information, including date of preparation or last revision: Disclaimer

Other information, including date of preparation or last revision: List of abbreviations



US - OSHA SAFETY DATA SHEET

Issue Date 24-Apr-2015

Revision Date 26-Oct-2017

Version 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name TUBERSOL®

Other means of identification

Product Information 10-test vial, 1 mL (NDC 49281-752-78); package of 1 vial, (NDC 49281-752-21)
50-test vial, 5 mL (NDC 49281-752-98); package of 1 vial, (NDC 49281-752-22)

Synonyms Tuberculin Purified Protein Derivative (Mantoux)

Recommended use of the chemical and restrictions on use

Recommended Use Aid diagnosis of tuberculosis infection (TB) in persons at increased risk of developing active disease.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address

Sanofi Pasteur
1 Discovery Drive
Swiftwater, PA 18370

Emergency telephone number

Company Phone Number 1-800-VACCINE (1-800-822-2463)

24 Hour Emergency Phone Number 1-570-957-4400

Emergency Telephone 1-570-957-4400

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Not classified.

Physical hazards

Not classified.

OSHA Regulatory Status

This product is a vaccine that is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows through the sheet.

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance Clear colorless liquid

Physical state Liquid

Odor Not available.

Hazards not otherwise classified (HNOC)

Not classified as a hazardous substance.

TUBERSOL®

Revision Date 26-Oct-2017

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Tuberculin Purified Protein Derivative (Mantoux)

Chemical Name	CAS No.	Weight-%
Purified Protein derivative of Mycobacterium tuberculosis	N/A	N/A
Sterile isotonic phosphate buffered saline	N/A	q.s to 100

Note: Ingredients below reportable levels are not listed.

4. FIRST AID MEASURES

First aid measures

Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin Contact	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
Inhalation	In case of inhalation, remove to fresh air. If breathing is difficult, administer oxygen. Seek medical attention immediately.
Ingestion	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention if needed. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Do not use mouth-to-mouth method if victim ingested or 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.

Most important symptoms and effects, both acute and delayed

Symptoms Induration at test site if test is positive for TB.

Indication of any immediate medical attention and special treatment needed

Note to physicians 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 None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.

Explosion data

Sensitivity to Mechanical Impact Not available.

Sensitivity to Static Discharge None known.

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 Wear appropriate personal protective equipment (see Section 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 Wipe up with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 2° to 8°C (35° to 46°F). Do not freeze. Protect from light.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls Used as supplied, no special engineering controls are needed when administering the vaccine.

Individual protection measures, such as personal protective equipment

Eyeface protection In laboratory or industrial settings, safety glasses with side shields are recommended.

Skin and body protection In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory protection Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Odor	Not available.
Appearance	Clear colorless liquid	Odor threshold	Not available.
Color	Clear		

Property	Values	Remarks • Method
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	

TUBERSOL®

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Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability Limit in Air	
Upper flammability limit:	Not available.
Lower flammability limit:	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY**Reactivity**

Not reactive under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal handling.

Hazardous polymerization	Hazardous polymerization does not occur.

Conditions to avoid

Not available.

Incompatible materials

Not available.

Hazardous Decomposition Products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Product Information	No data available.
Inhalation	No impact known or expected under normal use.
Eye contact	No impact known or expected under normal use.
Skin Contact	No impact known or expected under normal use.
Ingestion	No impact known or expected under normal use.

Information on toxicological effects

Symptoms Induration at test site if test is positive for TB.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Irritation	Not available.
Corrosivity	Not available.
Sensitization	Not available.
Germ cell mutagenicity	TUBERSOL has not been evaluated for its mutagenic potential.
Carcinogenicity	TUBERSOL has not been evaluated for its carcinogenic potential.
Reproductive toxicity	Pregnancy Category C: Animal reproduction studies have not been conducted with TUBERSOL. It is also not known whether TUBERSOL can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It is not known whether TUBERSOL is excreted in human milk.
Developmental Toxicity	Not available.
Teratogenicity	Not available.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Chronic toxicity	Not available.
Subchronic toxicity	Not available.
Target Organ Effects	Not available.
Neurological effects	Not available.
Other adverse effects	Not available.
Aspiration hazard	Not available.

Numerical measures of toxicity - Product Information**12. ECOLOGICAL INFORMATION****Ecotoxicity**

Not available.

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Not available.

Other adverse effects

Not 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	Disposal should be in accordance with applicable regional, national and local laws and regulations.
US EPA Waste Number	Not applicable.
California Hazardous Waste Codes	Not applicable.

TUBERSOL®

Revision Date 26-Oct-2017

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated.
<u>TDG</u>	Not regulated.
<u>MEX</u>	Not regulated.
<u>ICAO (air)</u>	Not regulated.
<u>IATA</u>	Not regulated.
<u>IMDG</u>	Not regulated.
<u>RID</u>	Not regulated.
<u>ADR</u>	Not regulated.
<u>ADN</u>	Not regulated.

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 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).

US State Regulations

California Proposition 65

No component is on the Proposition 65 list.

U.S. State Right-to-Know Regulations

This drug is regulated by the Food and Drug Administration and is therefore exempt from State Right-to-Know Regulations.

TUBERSOL®

Revision Date 26-Oct-2017

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	24-Apr-2015
Revision Date	26-Oct-2017
Revision Note	Updated California Proposition 65 Information

Disclaimer

Sanofi Pasteur considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Sanofi Pasteur cannot be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet



SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Xylocaine/Xylocaine-MPF
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: January 08, 2009
SDS Revision Date: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Respiratory sensitisation. Category 1.
 Skin Sensitization. Category 1.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause an allergic skin reaction.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 In case of inadequate ventilation wear respiratory protection.
 IF ON SKIN: Wash with plenty of water.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF exposed or concerned: Get medical advice/attention.
 Specific treatment (see ... on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects: Possible adverse reactions include: lightheadedness, nervousness, drowsiness, bradycardia, hypotension, and allergic reactions. Occupational exposure has not been fully investigated.

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Possible adverse reactions include: lightheadedness, nervousness, drowsiness, bradycardia, hypotension, and allergic reactions. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a known history of hypersensitivity to local anesthetics of the amide type or to other components of Xylocaine®/Xylocaine®-MPF.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Lidocaine Hydrochloride	137-58-6	0.5 %, 1 %, 1.5 %, and 2 %	
Sodium Chloride	7647-14-5	For Isotonicity	
Methylparaben	99-76-3	1 mg/mL	
Note:	Xylocaine®-MPF does not contain methylparaben		

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Should be stored at room temperature, approximately 25°C (77°F). Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended topical purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/nppt/topics/respirators/) for a list of respirator types and approved suppliers.

Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	17 mmHg at 20°C
Percent Volatile:	Not established.
pH:	Approximately 6.5 (5.0-7.0)
Molecular Formula:	Mixture
Molecular Weight:	288.82
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Water reactive materials.

SECTION 11 : TOXICOLOGICAL INFORMATION

Lidocaine Hydrochloride :

Acute Toxicity:	LD50 IV Rat: 21 mg/kg LD50 IV Mouse: 15 mg/kg

Lidocaine Hydrochloride :

RTECS Number:	AN7525000
Ingestion:	Oral - Rat LD50: 317 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 220 mg/kg [Behavioral - Convulsions or effect on seizure threshold Behavioral - Rigidity (including catalepsy) Lungs, Thorax, or Respiration - Respiratory stimulation]
Other Toxicological Information:	Intravenous. - Human TDLo: 23 mg/kg [Behavioral - muscle contraction or spasticity Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Mouse LD50: 20 mg/kg [Behavioral - convulsions or effect on seizure threshold Vascular - BP lowering not characterized in autonomic section Lungs, Thorax, or Respiration - other changes] Intravenous. - Rabbit LDLo: 41 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Guinea pig LDLo: 65 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 39.4 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat LD50: 18 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 5 mg/kg [Vascular - BP lowering not characterized in autonomic section] Intravenous. - Rat TDLo: 2343 ug/kg/5M [Cardiac - change in rate] Intravenous. - Rat TDLo: 4688 ug/kg/5M [Vascular - BP lowering not characterized in autonomic section] Intravenous. - Rabbit TDLo: 3 mg/kg [Cardiac - change in rate Cardiac - cardiac output Vascular - BP lowering not characterized in autonomic section] Subcutaneous - Rat LD50: 335 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 238 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LD50: 120 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Human TDLo: 33.3 ug/kg [Behavioral - analgesia] Subcutaneous - Mouse TDLo: 50 mg/kg [Peripheral Nerve and Sensation - local anesthetic] Subcutaneous - Mouse TDLo: 150 mg/kg [Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat LD50: 133 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - other changes] Intraperitoneal. - Mouse LD50: 102 mg/kg [Peripheral Nerve and Sensation - local anesthetic Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia] Intraperitoneal. - Rat TDLo: 2 mg/kg [Blood - other changes]

Sodium Chloride :

RTECS Number:	VZ4725000
Eye:	Eye - Rabbit Standard Draize test.: 10 mg [Moderate]

Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Inhalation:	Inhalation - Rat LC50: >42 gm/m ³ /1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes] Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability] Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion] Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral] Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

Methylparaben :

RTECS Number:	DH2450000
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent) Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]
Ingestion:	Oral - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Ataxia] Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia] Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - shock Lungs, Thorax, or Respiration - respiratory depression] Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - tumors] Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight] Subcutaneous - Mouse TDLo: 165 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight] Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - somnolence (general depressed activity) Behavioral - ataxia] Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	NA Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Lidocaine Hydrochloride :

TSCA Inventory Status: Listed
EINECS Number: 205-302-8
Canada DSL: Listed

Sodium Chloride :

TSCA Inventory Status: Listed
EINECS Number: 231-598-3
Canada DSL: Listed

Methylparaben :

TSCA Inventory Status: Listed
EINECS Number: 202-785-7
Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 2
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X

SDS Creation Date: January 08, 2009

SDS Revision Date: June 01, 2015

Disclaimer:

The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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SAFETY DATA SHEET**ZEP ACCLAIM AB HAND SOAP ANTI-BAC_4-1GL**

Version 1.4

Revision Date 01/22/2021

Print Date 05/22/2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Material name : ZEP ACCLAIM AB HAND SOAP ANTI-BAC_4-1GL

Material number : 000000000000314924

Manufacturer or supplier's details

Company : Zep Inc.

Address : 350 Joe Frank Harris Parkway, SE
Emerson, GA 30137

Telephone : 404-352-1680

Emergency telephone numbers**For SDS Information** : Compliance Services 1-877-428-9937**For a Medical Emergency** : 877-541-2016 Toll Free - All Calls Recorded**For a Transportation
Emergency** : CHEMTREC: 800-424-9300 - All Calls Recorded.
In the District of Columbia 202-483-7616**Recommended use of the chemical and restrictions on use**

This product is labeled as an over-the-counter (non-prescription) drug under the Food and Drug administration (FDA) regulations of the United States. The warnings presented below in this Safety Data Sheet (SDS) comply with the 2012 OSHA Hazard Communication Standard (GHS - Globally Harmonized System of Classification and Labeling). The requirements for the labeling and warnings of FDA products may differ from those required for GHS based hazard communication.

SECTION 2. HAZARDS IDENTIFICATION**Emergency Overview**

Appearance	viscous liquid
Colour	clear, red, orange
Odour	No data available

GHS Classification

Eye irritation : Category 2A

GHS label elements

Hazard pictograms :

Exclamation
mark

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

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Precautionary statements : **Prevention:**
 P264 Wash skin 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration [%]
glycerol	56-81-5	>= 1 - < 3
cetrimonium chloride	112-02-7	>= 1 - < 3
Fatty acids, C8-18 and C18-unsatd., compds. with diisopropanolamine	68855-69-6	>= 1 - < 3
N-[3-(dimethylamino)propyl]dodecanamide N-oxide	61792-31-2	>= 1 - < 3

The exact percentages of disclosed substances are withheld as trade secrets.

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
 Show this safety data sheet to the doctor in attendance.
 Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.
 If symptoms persist, call a physician.

In case of skin contact : This product is formulated for use on skin but should always be immediately washed off with plenty of water. Discontinue use if irritation and redness develop. If conditions persist for more than 72 hours, consult a physician.

In case of eye contact : Remove contact lenses.
 Protect unharmed eye.
 Keep eye wide open while rinsing.
 If eye irritation persists, consult a specialist.
 If in eyes, rinse with water for 15 minutes.

If swallowed : Keep respiratory tract clear.
 Never give anything by mouth to an unconscious person.
 DO NOT induce vomiting unless directed to do so by a physician or poison control center.
 If symptoms persist, call a physician.

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Most important symptoms and effects, both acute and delayed	: Effects are immediate and delayed. Symptoms may include irritation, redness, pain, and rash. Causes serious eye irritation. Review section 2 of SDS to see all potential hazards.
Notes to physician	: Treat symptomatically. Symptoms may be delayed.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Dry chemical Foam Alcohol-resistant foam Carbon dioxide (CO ₂)
Unsuitable extinguishing media	: High volume water jet
Specific hazards during firefighting	: Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	: Carbon dioxide (CO ₂) Carbon monoxide Smoke Nitrogen oxides (NO _x)
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Further information	: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Material can create slippery conditions. Use non-slip safety shoes in areas where spills or leaks can occur. Refer to protective measures listed in sections 7 and 8.
Environmental precautions	: Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains, inform respective authorities.
Methods and materials for containment and cleaning up	: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

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SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : For personal protection see section 8.
Avoid contact with eyes.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
- Materials to avoid : No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (mist, total dust)	15 mg/m ³	OSHA Z-1
		PEL (Mist - total fraction)	10 mg/m ³	CAL PEL
		PEL (Mist - respirable fraction)	5 mg/m ³	CAL PEL
		TWA (Mist - total dust)	10 mg/m ³	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m ³	OSHA P0

Engineering measures : effective ventilation in all processing areas

Personal protective equipment

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

Hand protection
Remarks : No special protection is required.

Eye protection : Eye protection is not required while washing with this product.
In the workplace, the use of safety glasses is recommended to

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avoid eye exposure during the handling of containers or during spill clean-up.
Remove respiratory and skin/eye protection only after vapours have been cleared from the area.

Skin and body protection : No special protection is required.

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : viscous liquid

Colour : clear, red, orange

Odour : No data available

Odour Threshold : No data available

pH : 5 - 6

Melting point/freezing point : No data available

Boiling point : 100 °C

Flash point :
does not flash

Evaporation rate : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Density : 1.015 g/cm³

Solubility(ies)

Water solubility : completely soluble

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Stable

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Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No decomposition if stored and applied as directed.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION**Potential Health Effects**

Aggravated Medical Condition	: None known.
Symptoms of Overexposure	: Effects are immediate and delayed. Symptoms may include irritation, redness, pain, and rash. Causes serious eye irritation. Review section 2 of SDS to see all potential hazards. Treat symptomatically. Symptoms may be delayed.

Carcinogenicity:

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Acute toxicity**Product:**

Acute oral toxicity	: Acute toxicity estimate : 3,549 mg/kg Method: Calculation method
Acute inhalation toxicity	: Acute toxicity estimate : > 200 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method

Skin corrosion/irritation**Product:**

Result: No skin irritation

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Serious eye damage/eye irritation**Product:**

Remarks: Irritating to eyes.

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Aspiration toxicity

No data available

Further information**Product:**

Remarks: No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential**Product:**Partition coefficient: n- : Remarks: No data available
octanol/water**Components:****glycerol :**

Partition coefficient: n- : log Pow: -1.76

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octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information

: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal., Harmful to aquatic life.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues

: The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Dispose of in accordance with local regulations.

Contaminated packaging

: Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.**SECTION 14. TRANSPORT INFORMATION**Transportation Regulation: 49 CFR (USA):
NOT REGULATED AS DANGEROUS GOODS OR HAZARDOUS MATERIALTransportation Regulation: IMDG (Vessel):
NOT REGULATED AS DANGEROUS GOODS OR HAZARDOUS MATERIALTransportation Regulation: IATA (Cargo Air):
NOT REGULATED AS DANGEROUS GOODS OR HAZARDOUS MATERIALTransportation Regulation: IATA (Passenger Air):
NOT REGULATED AS DANGEROUS GOODS OR HAZARDOUS MATERIAL

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Transportation Regulation: TDG (Canada):
NOT REGULATED AS DANGEROUS GOODS OR HAZARDOUS MATERIAL

The product as delivered to the customer conforms to packaging requirements for shipment by road under US Department of Transportation (DOT) regulations. Additional transportation classifications noted above are for reference only, and not a certification or warranty of the suitability of the packaging for shipment under these alternative transport regulations.

SECTION 15. REGULATORY INFORMATION

TSCA list : No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

EPCRA - Emergency Planning and Community Right-to-Know Act**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 : Serious eye damage or eye irritation

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:

DSL All components of this product are on the Canadian DSL
TSCA On TSCA Inventory

For information on the country notification status for other regions please contact the manufacturer's regulatory group.

Inventory Acronym and Validity Area Legend:

SAFETY DATA SHEET**ZEP ACCLAIM AB HAND SOAP ANTI-BAC_4-1GL**

Version 1.4

Revision Date 01/22/2021

Print Date 05/22/2021

TSCA (USA), DSL (Canada), NDSL (Canada)

SECTION 16. OTHER INFORMATION**Further information****NFPA:**

HEALTH	2
FLAMMABILITY	0
INSTABILITY	0
SPECIAL HAZARD.	

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme

HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

OSHA - GHS Label Information:

Hazard pictograms

Exclamation
mark

Signal word

: **Warning:**

Hazard statements

: Causes serious eye irritation.

Precautionary statements

Prevention: Wash skin thoroughly after handling. Wear 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.

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We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind. The information in this document applies to this specific material as supplied. It may not be valid for this material if it is used in combination with any other materials. Users should make their own investigations to determine the suitability and applicability of the information for their particular purposes. This SDS has been prepared by the Compliance Services organization supporting this manufacturer, supplier or distributor.

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General



Flexion Therapeutics, Inc.
10 Mall Road - Suite 301, Burlington, MA 01803
Main: +1 (781) 305-7777
Fax: +1 (781) 202-3399
E-mail: sds@flexiontherapeutics.com

Emergency telephone number

ChemTel Inc. (Available 24/7, 365 days/year):
+1 (800) 255-3924 (US and Canada)
+01 (813) 248-0585 (International)

Product identifier

FX006 Extended-Release (ER) formulation (in vials)

Synonyms

Microsphere-encapsulated triamcinalone acetonide (triamcinolone); 9 α -Fluoro-11 β ,16 α ,17 α ,21-tetrahydroxy-1,4-pregnadiene-3,20-dione 16,17-acetonide

Trade names

Zilretta® (triamcinolone acetonide extended-release injectable suspension)

Chemical family

Mixture - containing synthetic molecules

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

Bulk formulated pharmaceutical mixture/ Formulated pharmaceutical product/ mixture packaged in final form for patient use; the active ingredient (triamcinolone) is a potent, anti-inflammatory agent.

Note

This SDS is written to address potential worker health and safety issues associated with the handling of the formulated drug product.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Consult prescribing/packaging information. **The classification and labeling listed below is for bulk drug product.**

Globally Harmonized System [GHS]

Reproductive Toxicity - Category 1B.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ...continued

GHS hazard pictogram**GHS signal word**

Danger

GHS hazard statements

H360D - May damage the unborn child.

GHS precautionary statements

P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear eye/face protection. P308 + P313 - IF exposed or concerned: get medical advice/attention. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards

FX006 is an injectable formulation consisting of triamcinolone acetonide (triamcinolone) encapsulated in copolymer microspheres indicated for the treatment of osteoarthritis. FX006 is administered by intra-articular injection at doses of 40 mg. The most commonly reported adverse effects associated with FX006 include arthralgia (joint pain), joint swelling, and contusions (bruising).

Therapeutic use of corticosteroids is associated with reversible suppression of the hypothalamus-pituitary-adrenal axis, possibly leading to acute adrenal insufficiency upon withdrawal.

Excessive systemic exposure may result in effects that include fluid and electrolyte abnormalities (*e.g.*, edema, low serum potassium), hypertension, hyperglycemia, and Cushing's syndrome (characterized by fat redistribution, bruising, acne, and hirsutism).

Based on epidemiological studies and developmental toxicity seen in animals, the potential for fetal harm cannot be excluded. Corticosteroids are generally teratogenic in laboratory animals at relatively low doses, and triamcinolone is 200 times more effective at producing cleft palate than other corticosteroids.

Note

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Poly(DL-lactide-co-glycolide)	26780-50-7	N/A	~75 %	Not classified
Triamcinolone Acetonide	76-25-5	200-948-7	~25 %	ATO4: H302; RT1B: H360D

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

Note	The ingredient(s) listed above are considered hazardous. Poly(DL-lactide-co-glycolide) is included because it makes up the microspheres that encapsulate the pharmacologically active ingredient. See Section 16 for full text of GHS classifications.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures	
Immediate Medical Attention Needed	Yes
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, and fluorine-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. High concentrations of finely divided airborne organic particles can potentially explode if ignited.

SECTION 5 - FIREFIGHTING MEASURES...continued

Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If vials are broken or crushed, and product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	If vials are broken or crushed, and product is released or spilled, DO NOT RAISE DUST. Dispose of broken vials in a sharps container. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Follow recommendations for handling bulk formulated pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing dust.
Conditions for safe storage including any incompatibilities	Store refrigerated between 2 to 8° C away from incompatible materials. Keep out of reach of children. Protect from light, moisture, and excessive heat.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note	Wash hands, face and other potentially exposed areas immediately in the event of physical contact. Dispose of broken vials/syringes in a sharps container.

**Control Parameters/
Occupational Exposure
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Poly(DL-lactide-co-glycolide)	--	--	--
Triamcinolone Acetonide	Russia	STEL	1 µg/m ³ "skin"

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued

Exposure/Engineering controls	None required for normal handling of packaged product. If vials are crushed/broken: Control exposures to below the OEL. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.
Respiratory protection	None required for normal handling of packaged product. If vials are crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.
Hand protection	None required for normal handling of packaged product. If vials are crushed/broken: Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Skin protection	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Powder, granules, or pellets (in vials).
Color	White to off-white.
Odor	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Odor threshold	No information identified.
pH	Not applicable
Melting point/ freezing point	269-271 °C (triamcinolone).
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	7.2×10^{-15} mm Hg (at 25 °C) (triamcinolone).
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Practically insoluble (triamcinolone).
Solvent solubility	Sparingly soluble in dehydrated alcohol, chloroform, and methyl alcohol (triamcinolone).
Partition coefficient (<i>n</i>-octanol/water)	1.16 (triamcinolone).
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular formula	Not applicable (Mixture).
Molecular weight	Not applicable (Mixture).

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Chemically stable for 24 months under recommended storage conditions.

SECTION 10 - STABILITY AND REACTIVITY...continued

Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	No information identified.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note **Limited data for this mixture were identified. The following data primarily describe the active ingredient.**

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact, eye contact, and ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Poly(DL-lactide-co-glycolide)	--	--	--	--
Triamcinolone Acetonide	LD ₅₀	Oral	Mouse	2168 mg/kg
	LD ₅₀	Oral	Rat	1451 mg/kg
	LD ₅₀	Subcutaneous	Mouse	132 mg/kg
	LD ₅₀	Subcutaneous	Rat	13.1 mg/kg

Irritation/Corrosion Triamcinolone was only slightly irritating to rabbit eyes.

Sensitization Triamcinolone was not sensitizing to guinea pigs when topically applied as a suspension containing 40 mg/mL in saline.

STOT-single exposure Microsphere localization and generally mild, localized foreign body response was noted in dogs administered single intra-articular (IA) doses of FX006 at doses as low as 2.1 mg. Effects were reversible following microsphere degradation (3-4 months).

STOT-repeated exposure/Repeat-dose toxicity Following repeated, intermittent IA administration of FX006 in dogs, local and reversible immune response to the microspheres was seen at all doses tested (≥ 6.25 mg). Reversible structural and cellular changes in the cartilage, consistent with effects of triamcinolone, were noted. Subacute toxicity studies in rats, rabbits and dogs were conducted by conventional routes of administration and by inhalation of aerosolized triamcinolone (dosing information was not identified). Findings in all studies were reported as being typical of glucocorticoids, but no gross histopathological or structural changes suggestive of untoward effects were noted.

Reproductive toxicity Triamcinolone did not impair fertility in male and females rats given oral doses of 15 μ g/kg/day. However, maternal toxicity was noted at 8 or 15 μ g/kg/day in a few females exhibiting difficult and prolonged delivery.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Developmental toxicity	Triamcinolone was teratogenic in rats and rabbits treated with inhaled doses as low as 20 µg/kg/day. Effects included cleft palate, hydrocephaly, and skeletal defects. In monkeys treated with inhaled doses of 500 µg/kg/day, central nervous system and cranial defects were observed. Developmental toxicity (including increases in fetal resorptions and stillbirths and decreases in pup body weight and survival) also occurred in rats at maternally toxic doses (≥5 µg/kg/day).
Genotoxicity	Triamcinolone was negative in the Ames bacterial mutagenicity assay and the <i>in vitro</i> Chinese Hamster Ovary forward mutation assay. Triamcinolone was positive in an <i>in vivo</i> mouse micronucleus test.
Carcinogenicity	No evidence of treatment-related carcinogenicity was noted in rats and mice treated orally with 1.0 and 3.0 µg/kg/day triamcinolone, respectively, for 2 years. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data available.
Human health data	See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity			
<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Poly(DL-lactide-co-glycolide)	--	--	--
Triamcinolone Acetonide	--	--	--
Additional toxicity information	No data available.		
Persistence and Degradability	Poly(DL-lactide-co-glycolide) is readily biodegradable. Based on a log K _{OW} of 1.16, triamcinolone is not likely to persist in the environment.		
Bioaccumulative potential	No data available.		
Mobility in soil	No data available.		
Results of PBT and vPvB assessment	No data available.		
Other adverse effects	No data available.		
Note	Ecological characteristics of this mixture were not available. Releases to the environment should be avoided. Data above describe specific ingredients, where applicable.		

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Due to lack of data, avoid release to the environment.
Special precautions for users	Mixture not fully tested - avoid exposure.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
TSCA status	Not listed
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. RT1B - Reproductive toxicity Category 1B. H360D - May damage the unborn child.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Issue Date	6 October 2017
Revisions	This is the second version of this SDS. Updated general format for compliance with most recent regulatory requirements in the US, EU, and Canada. Updated classification in Section 2 and data in Section 11.
Disclaimer	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 and protections 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 because it is a potent pharmaceutical product. 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.