Ashland
5/23/2021

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SAFETY DATA SHEET

1. Identification

Product identifier	**BD Vacutainer® Buffered Sodium Citrate Collection Tubes**
Other means of identification	
Product code	368932, 369704, 369714, 368026, 366351, 366392, 366393, 366394, 366395, 366415, 367716
Recommended use	For blood collection and analysis.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company name	BD Diagnostics, PreAnalytical Systems
Address	1 Becton Drive Franklin Lakes, NJ 07417-1885
Telephone	800-631-0174
Contact person	Technical Services
Emergency telephone	Chemtrec US 1-800-424-9300 EU 703-527-3887
E-mail	pas_tech_services@bd.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	This material is not considered hazardous by the OSHA Hazard Communication Standard, OSHA 29 CFR 1910.1200.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

4. First-aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Flush eyes with water as a precaution. If irritation occurs, get medical assistance.
Ingestion	Rinse mouth. Get medical attention if any discomfort occurs.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.

General information	No specific first aid measures noted.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases may be formed.
Special protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid contact with eyes and prolonged skin contact. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	Wipe up spilled material and place in a suitable container for disposal. Following product recovery, flush area with water. For waste disposal, see Section 13 of the SDS.
Environmental precautions	Environmental manager must be informed of all major spillages.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes and prolonged skin contact. Observe good laboratory hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in a cool, dry, well-ventilated place. Keep container closed. Store away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Toluene (CAS 108-88-3)	Ceiling	300 ppm
	TWA	200 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Toluene (CAS 108-88-3)	TWA	20 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Toluene (CAS 108-88-3)	STEL	560 mg/m3
		150 ppm
	TWA	375 mg/m3
		100 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Toluene (CAS 108-88-3)	0.3 mg/g	o-Cresol, with hydrolysis	Creatinine in urine	*
	0.03 mg/l	Toluene	Urine	*
	0.02 mg/l	Toluene	Blood	*

* - For sampling details, please see the source document.

Exposure guidelines	No exposure limits noted for ingredient(s).
Appropriate engineering controls	No particular ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection	Risk of contact: Wear approved safety goggles.
Skin protection	
Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier.
Skin protection	
Other	No protection is ordinarily required under normal conditions of use.
Respiratory protection	Under normal conditions, respirator is not normally required.
Thermal hazards	None.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.
Color	Colorless.
Odor	Odorless.
Odor threshold	Not applicable.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not applicable.
Flammability limit - upper (%)	Not applicable.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Completely soluble in water.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.

Hazardous decomposition products	None expected under normal conditions of use.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged contact may cause dryness of the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization	Based on available data, the classification criteria are not met.
Skin sensitization	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity	Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.
Chronic effects	No specific chronic health impact noted.
Further information	No additional adverse health effects noted.

12. Ecological information

Ecotoxicity	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	This product is water soluble and may disperse in soil.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Do not discharge into drains, water courses or onto the ground.
Hazardous waste code	Not regulated.
Waste from residues / unused products	Dispose of waste and residues in accordance with local authority requirements.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Toluene (CAS 108-88-3)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 17-May-2016

Revision date -

Version # 01

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings

References
ACGIH: American Conference of Governmental and Industrial Hygienists.
US. IARC Monographs on Occupational Exposures to Chemical Agents
IARC Monographs. Overall Evaluation of Carcinogenicity
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices

Disclaimer To the best of our knowledge, the information contained herein is accurate. However, neither BD nor any of its subsidiaries assumes any liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

US - OSHA SAFETY DATA SHEET

11/24/14 **Revision Date** **Version** 1

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

Product identifier

Product Name BENADRYL Allergy Dye-Free LIQUI-GELS

Other means of identification

Product Code MCHC-BDRALLLG
C-1261

Synonyms Benadryl dye-free liquid gels
Benadryl liquid gels

Recommended use of the chemical and restrictions on use

Recommended Use Temporarily relieves these symptoms due to hay fever or other respiratory allergies: runny nose; sneezing; itchy, watery eyes; itching of the nose or throat.

Temporarily relieves these symptoms due to the common cold: runny nose, sneezing.

Recommended Restrictions None Known.

Details of the supplier of the safety data sheet

Supplier Address
McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.
7050 Camp Hill Rd.
Fort Washington, PA
10934-2299

Emergency telephone number

Company Phone Number (215) 273-7000

24 Hour Emergency Phone Number For 24-hour emergency assistance, call the 3E Company at 1 (877)-236-9871
Provide the technician with the following product tracking code: 2277

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified

Physical hazards
Not Classified.

OSHA Regulatory Status
Over the counter drugs in their solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

Label elements

Emergency Overview

Hazard statements
This material does not meet the criteria for classification.

Hazard Symbol
None

Signal Word
None

Appearance Clear, oblong, soft, gelatin capsule printed "BENADRYL" on one side with white ink **Physical state** Soft Gelatin Capsule **Odor** Not available.

Precautionary Statements - Prevention
Not available

Precautionary Statements - Response
No specific first aid measures noted.

Precautionary Statements - Storage
Store at 20 -25 °C (68 - 77 °F). Avoid high humidity and excessive heat. Protect from light.

Precautionary Statements - Disposal
Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards not otherwise classified (HNOC)
Not classified.

Other Information
Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Benadryl dye-free liquid gels
Benadryl liquid gels.

Chemical Name	CAS No.	Weight-%
Diphenhydramine Hydrochloride USP	147-24-0	1-5
Glycerin	56-81-5	1-15
Polyethylene Glycol	25322-68-3	20-40

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 Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, then thoroughly flush the area with water. If irritation persists, seek medical advice.

Inhalation If symptomatic, move to fresh air. Get medical attention if symptoms persist.

Ingestion If symptomatic, seek medical advice. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms Diphenhydramine is a potent anticholinergic agent. This activity is responsible for the side-effects of dry mouth and throat, increased heart rate, pupil dilation, urinary retention, constipation, and, at high doses, hallucinations or delirium.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not applicable.

Explosion data

Sensitivity to Mechanical Impact None known.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

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 If dry, vacuum and place into proper container for disposal. If wet, collect or scrape up and ensure area is thoroughly cleaned.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep only in the original container. Store at 20 - 25 °C (68 - 77 °F). Avoid high humidity and excessive heat. Protect from light. Keep away from food, drink, and animal feedingstuffs. Keep out of reach of children.

Incompatible materials None known based on information supplied. Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Biological limit values No biological limits noted for this ingredient.

Exposure Guidelines Based on a review of animal and clinical literature, an Occupational Exposure Limit (OEL) of 139 µg/m^3 is recommended as an 8-hour TWA for Diphenhydramine Hydrochloride.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin 56-81-5	-	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	-

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Hand protection Use protective gloves. None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards Not applicable.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Soft Gelatin Capsule		
Appearance	Clear, oblong, soft, gelatin capsule printed "BENADRYL" on one side with white ink	**Odor**	Not available.
Color	Clear	**Odor threshold**	Not available.

Property	**Values**	**Remarks • Method**
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
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.	
Lower explosive limit:	Not available.	
Upper explosive limit:	Not available.	
Oxidizing properties	Not available.	

10. STABILITY AND REACTIVITY

Reactivity
Stable at normal conditions.

Chemical stability
Stable.

Possibility of Hazardous Reactions
Hazardous polymerization does not occur.

Conditions to avoid
Low and elevated temperatures. High humidity and light.

Incompatible materials
None known based on information supplied. Strong oxidizing agents.

Hazardous Decomposition Products
Carbon oxides. Silicon oxides. Nitrogen oxides. Sodium oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information No data available

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Eye contact This product is not expected to be an eye hazard.

Skin Contact This product is not expected to be a skin hazard.

Ingestion Unknown.

Acute Effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Diphenhydramine Hydrochloride USP 147-24-0	= 500 mg/kg (Rat) = 160 mg/kg (Mouse)	= 280 mg/kg (Rat)	-	= 42 mg/kg (Rat) = 29 mg/kg (Mouse)
Glycerin 56-81-5	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m^3 (Rat) 1 h	-
Polyethylene Glycol 25322-68-3	= 28 g/kg (Rat)	> 20 mL/kg (Rabbit) > 20 g/kg (Rabbit)	-	

Acute intravenous lowest observed toxic dose (TDLo) was 5 mg/kg in rats and 1 mg/kg in mice.

Information on toxicological effects

Symptoms Diphenhydramine is a potent anticholinergic agent. This activity is responsible for the side-effects of dry mouth and throat, increased heart rate, pupil dilation, urinary retention, constipation, and, at high doses, hallucinations or delirium.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization Not available.
Germ cell mutagenicity Not available.
Carcinogenicity Not available.
Reproductive toxicity Not available.
STOT - single exposure Not classified.
STOT - repeated exposure Not classified.
Aspiration hazard Due to the physical form of the product it is not an aspiration hazard.

Numerical measures of toxicity - Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Dispose in accordance with applicable federal, state, and local regulations.
Local disposal regulation	Dispose in accordance with local regulations.
Hazardous waste code	Hazardous waste codes should be determined in accordance with hazardous waste regulatory authorities
Waste from residue / unused packaging	Dispose in accordance with applicable regulations.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT	Not regulated as a hazardous material by DOT.
IATA	Not regulated as a dangerous good.
IMDG	Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	This substance/mixture is not intended to be transported in bulk

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	Complies
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Complies

Legend:

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

US Federal Regulations

US OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Over-the-counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous listed.

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

Drug Enforcement Administration (DEA) List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))
Not regulated

DEA Exempt Chemical Mixtures Code Number
Not regulated

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

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)

Safe Drinking Water Act (SDWA)
Not regulated

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

CA State Regulations
This product does not contain a chemical known to the State of California to cause cancer, birth defects, or other reproductive harm

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
Glycerin 56-81-5	X	X	X

U.S. EPA Label Information
EPA Pesticide Registration Number Not available

16. OTHER INFORMATION

Revision Date
Revision Note
Not 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 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

Issue Date 14-Dec-2007 **Revision Date** 13-Apr-2015 **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name	Betadine® (povidone-iodine, 10%) Solution Swabsticks
Synonyms	PVP-I
Recommended Use	This product is a topical microbicide
Uses advised against	Not for oral use.
Distributor Address	Purdue Products L.P. One Stamford Forum 201 Tresser Boulevard Stamford, Connecticut 06901-3431 (888) 726-7535
24 Hour Emergency Phone Number	Chemtrec (800) 424-9300 For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

This product is not considered hazardous by the 2012 OSHA Hazard Communications standard (29 CFR 1910.1200).

Serious eye damage/eye irritation	Category 2B

Emergency Overview

Signal Word Warning

Hazard Statements
Causes serious eye irritation

Appearance Reddish-brown **Physical state** Liquid **Odor** Characteristic odor

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling. Prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions. In pre-operative prepping, avoid "pooling" beneath the patient.

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.

Hazards Not Otherwise Classified (HNOC)
Not Applicable.

Other Information
Causes mild skin irritation
0% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Povidone Iodine	25655-41-8	5-10
Sodium hydroxide	1310-73-2	<1

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 not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidential ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. 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 No information available.

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 No information available.

Specific hazards arising from the chemical
No information available.

Explosion Data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

Other Information Not Applicable.

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

Advice on safe handling Avoid contact with skin, eyes or clothing.

Conditions for safe storage, including any incompatibilities

Storage conditions Keep container tightly closed in a dry and well-ventilated place.

Incompatible materials Strong alkalis or reducing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m^3	TWA: 2 mg/m^3	IDLH: 10 mg/m^3 Ceiling: 2 mg/m^3

Engineering Controls Handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

Individual Protection Measures (Personal Protective Equipment)

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.

Respiratory protection Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used they are to be NIOSH approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state Liquid
Appearance Reddish-brown
Odor Characteristic odor
Color Reddish-brown
Odor threshold No information available.

Property	Values	Remarks • Method
pH	No information available.	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	> 93.3 °C / > 200 °F	CC (closed cup)
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	No information available.	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	No information available.	
Autoignition temperature	No information available.	
Decomposition temperature	No information available.	
Kinematic viscosity	No information available.	
Dynamic viscosity	No information available.	
Explosive properties	No information available.	
Oxidizing properties	No information available.	

Other Information

Softening point	No information available.
Molecular weight	No information available.
VOC content; (%)	No information available.
Density	No information available.
Bulk density	No information available.

10. STABILITY AND REACTIVITY

Reactivity A mixture of equal parts of a 10% povidone iodine solution and hydrogen peroxide 3% exploded about 100 minutes after mixing.

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions No information available.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid None known based on available information.

Incompatible materials Strong alkalis or reducing agents.

Hazardous decomposition products Will not decompose under conditions of usual handling.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information Betadine® Solution has not undergone toxicity testing in animals. The information presented below is for povidone iodine.

Inhalation

Povidone iodine: Overexposure from breathing aerosols and/or iodine vapors may cause irritation to the respiratory tract, bronchitis and absorption through the lungs.

High concentrations of iodine in the blood from inhalation or ingestion may cause thyroid disorder (hyperthyroidism), renal disturbances, acidosis, and electrolyte disturbances such as increased iodine levels and severe hyponatremia.

Conditions that may be aggravated by exposure to povidone iodine: asthma, chronic bronchitis, and thyroid disorders.

Eye contact

Povidone iodine: Povidone iodine has been reported to be a mild skin and eye irritant in animals.

Skin contact

Povidone iodine: Povidone iodine has been reported to be a mild skin and eye irritant in animals.

Ingestion

May be harmful if swallowed.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	-	1350 mg/kg (Rabbit)	-
Povidone Iodine	8 g/kg (Rat)	-	-
Polyvinylpyrrolidone	100 g/kg (Rat)	-	-
Iodine	14 g/kg (Rat)	-	-
Pareth 25-9	2 g/kg (Rat) 1600 mg/kg (Rat)	2500 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms

No information available.

Skin corrosion/irritation

Betadine® Solution is generally non-irritating to skin. However, prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions. Povidone iodine may cause skin sensitization.

Sensitization

Povidone iodine: Negative in a human insult patch test as a primary skin irritant. A few cases of dermal sensitivity exist. Chemical-like burn can occur if pooled solution is retained against a patient's skin for several hours while under pressure such as during prolonged hospital procedures (PVP-1 solution, 1% available iodine).

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Germ cell mutagenicity

Povidone iodine:
Bacterial mutagenicity: negative
Bone marrow (hamster): negative
Dominant lethal assay (mouse): negative
Mouse lymphoma: negative
Mouse micronucleus: negative

Carcinogenicity

Povidone iodone: No information available.

Reproductive toxicity

Caused toxicity in maternal and fetal rabbits without congenital defects. Large scale case-control studies did not increase congenital abnormalities during pregnancy and vaginal treatment.

STOT-single exposure

No information available.

STOT-repeated exposure

No information available.

Chronic Toxicity

Long term testing of Povidone in dogs (12 months) and 2 year in dogs and rats did not cause any effects of note.

Subchronic toxicity Povidone iodine: In a 12-week dietary study in rats, ingestion of povidone iodine at an average povidone iodine dosage of approximately 75 to 750 mg/kg/day produced a dose-dependent increase in serum protein-bound iodine and nonspecific, reversible microscopic changes in the thyroid. No other gross or microscopic povidone iodine-induced changes were observed. At equivalent iodine dosages, dietary potassium iodide produced similar thyroid changes of equal or greater severity.

Aspiration hazard No information available.

Acute toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document.

Oral LD50 8036 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium hydroxide		LC50 96 h = 45.4 mg/L (Oncorhynchus mykiss - static)		

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Do not reuse container.

Chemical Name	California Hazardous Waste Status
Sodium hydroxide 1310-73-2	Toxic Corrosive

14. TRANSPORT INFORMATION

DOT Not regulated.

IATA Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA	Not determined.
DSL	Not determined.

Legend:

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).

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hydroxide 1310-73-2	1000 lb			X

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.

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium hydroxide 1310-73-2	1000 lb		RQ 1000 lb final RQ RQ 454 kg final RQ

US State Regulations

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

US State Right-to-Know Regulations
US EPA Label Information
EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

NFPA	**Health Hazards** 1	**Flammability** 0	**Instability** 0	**Physical and Chemical Properties** -
HMIS	**Health Hazards** 1	**Flammability** 0	**Physical Hazards** 0	**Personal protection** X

General Information No additional information.

Prepared By This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

Issue Date 14-Dec-2007

Revision Date	13-Apr-2015
Revision Note	SDS reformated for OSHA (GHS) 2012.

Disclaimer

The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

End of Safety Data Sheet

SAFETY DATA SHEET

Issue Date 14-Dec-2007 **Revision Date** 13-Apr-2015 **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name	Betadine® (povidone-iodine, 10%) Solution - OTC
Synonyms	PVP-I
Recommended Use	This product is a topical microbicide
Uses advised against	Not for oral use.
Distributor Address	Purdue Products L.P. One Stamford Forum 201 Tresser Boulevard Stamford, Connecticut 06901-3431 (888) 726-7535
24 Hour Emergency Phone Number	Chemtrec (800) 424-9300 For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

This product is not considered hazardous by the 2012 OSHA Hazard Communications standard (29 CFR 1910.1200).

Serious eye damage/eye irritation	Category 2B

Emergency Overview

Signal Word Warning

Hazard Statements
Causes serious eye irritation

Appearance Reddish-brown **Physical state** Liquid **Odor** Characteristic odor

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling. Prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions. In pre-operative prepping, avoid "pooling" beneath the patient.

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.

Hazards Not Otherwise Classified (HNOC)
Not Applicable.

Other Information
Causes mild skin irritation
0% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Povidone Iodine	25655-41-8	5-10
Sodium hydroxide	1310-73-2	<1

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 not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidential ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. 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 No information available.

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 No information available.

Specific hazards arising from the chemical
No information available.

Explosion Data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

Other Information Not Applicable.

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

Advice on safe handling Avoid contact with skin, eyes or clothing.

Conditions for safe storage, including any incompatibilities

Storage conditions Keep container tightly closed in a dry and well-ventilated place.

Incompatible materials Strong alkalis or reducing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m³	TWA: 2 mg/m³	IDLH: 10 mg/m³ Ceiling: 2 mg/m³

Engineering Controls Handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

Individual Protection Measures (Personal Protective Equipment)

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.

Respiratory protection Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used they are to be NIOSH approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state Liquid
Appearance Reddish-brown
Odor Characteristic odor
Color Reddish-brown
Odor threshold No information available.

Property	Values	Remarks • Method
pH	No information available.	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	> 93.3 °C / > 200 °F	CC (closed cup)
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	No information available.	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	No information available.	
Autoignition temperature	No information available.	
Decomposition temperature	No information available.	
Kinematic viscosity	No information available.	
Dynamic viscosity	No information available.	
Explosive properties	No information available.	
Oxidizing properties	No information available.	

Other Information

Softening point	No information available.
Molecular weight	No information available.
VOC content; (%)	No information available.
Density	No information available.
Bulk density	No information available.

10. STABILITY AND REACTIVITY

Reactivity A mixture of equal parts of a 10% povidone iodine solution and hydrogen peroxide 3% exploded about 100 minutes after mixing.

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions No information available.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid None known based on available information.

Incompatible materials Strong alkalis or reducing agents.

Hazardous decomposition products Will not decompose under conditions of usual handling.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information Betadine® Solution has not undergone toxicity testing in animals. The information presented below is for povidone iodine.

Inhalation

Povidone iodine: Overexposure from breathing aerosols and/or iodine vapors may cause irritation to the respiratory tract, bronchitis and absorption through the lungs.

High concentrations of iodine in the blood from inhalation or ingestion may cause thyroid disorder (hyperthyroidism), renal disturbances, acidosis, and electrolyte disturbances such as increased iodine levels and severe hyponatremia.

Conditions that may be aggravated by exposure to povidone iodine: asthma, chronic bronchitis, and thyroid disorders.

Eye contact

Povidone iodine: Povidone iodine has been reported to be a mild skin and eye irritant in animals.

Skin contact

Povidone iodine: Povidone iodine has been reported to be a mild skin and eye irritant in animals.

Ingestion

May be harmful if swallowed.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	-	1350 mg/kg (Rabbit)	-
Povidone Iodine	8 g/kg (Rat)	-	-
Polyvinylpyrrolidone	100 g/kg (Rat)	-	-
Iodine	14 g/kg (Rat)	-	-
Pareth 25-9	2 g/kg (Rat) 1600 mg/kg (Rat)	2500 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms

No information available.

Skin corrosion/irritation

Betadine® Solution is generally non-irritating to skin. However, prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions. Povidone iodine may cause skin sensitization.

Sensitization

Povidone iodine: Negative in a human insult patch test as a primary skin irritant. A few cases of dermal sensitivity exist. Chemical-like burn can occur if pooled solution is retained against a patient's skin for several hours while under pressure such as during prolonged hospital procedures (PVP-1 solution, 1% available iodine).

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Germ cell mutagenicity

Povidone iodine:
Bacterial mutagenicity: negative
Bone marrow (hamster): negative
Dominant lethal assay (mouse): negative
Mouse lymphoma: negative
Mouse micronucleus: negative

Carcinogenicity

Povidone iodone: No information available.

Reproductive toxicity

Caused toxicity in maternal and fetal rabbits without congenital defects. Large scale case-control studies did not increase congenital abnormalities during pregnancy and vaginal treatment.

STOT-single exposure

No information available.

STOT-repeated exposure

No information available.

Chronic Toxicity

Long term testing of Povidone in dogs (12 months) and 2 year in dogs and rats did not cause any effects of note.

Subchronic toxicity Povidone iodine: In a 12-week dietary study in rats, ingestion of povidone iodine at an average povidone iodine dosage of approximately 75 to 750 mg/kg/day produced a dose-dependent increase in serum protein-bound iodine and nonspecific, reversible microscopic changes in the thyroid. No other gross or microscopic povidone iodine-induced changes were observed. At equivalent iodine dosages, dietary potassium iodide produced similar thyroid changes of equal or greater severity.

Aspiration hazard No information available.

Acute toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document.

Oral LD50 8036 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium hydroxide		LC50 96 h = 45.4 mg/L (Oncorhynchus mykiss - static)		

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Do not reuse container.

Chemical Name	California Hazardous Waste Status
Sodium hydroxide 1310-73-2	Toxic Corrosive

14. TRANSPORT INFORMATION

DOT Not regulated.

IATA Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA	Not determined.
DSL	Not determined.

Legend:

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).

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hydroxide 1310-73-2	1000 lb			X

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.

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium hydroxide 1310-73-2	1000 lb		RQ 1000 lb final RQ RQ 454 kg final RQ

US State Regulations

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

US State Right-to-Know Regulations
US EPA Label Information
EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

NFPA	**Health Hazards** 1	**Flammability** 0	**Instability** 0	**Physical and Chemical Properties** -
HMIS	**Health Hazards** 1	**Flammability** 0	**Physical Hazards** 0	**Personal protection** X

General Information No additional information.

Prepared By This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

Issue Date 14-Dec-2007

Revision Date	13-Apr-2015
Revision Note	SDS reformated for OSHA (GHS) 2012.

Disclaimer

The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

End of Safety Data Sheet

SAFETY DATA SHEET

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

Product Identifier

Material Name: Mepivacaine Hydrochloride Injection, USP (Hospira, Inc.)

Trade Name: CARBOCAINE
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as 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

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
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)	**
Mepivacaine Hydrochloride	1722-62-9	217-023-9	Not Listed	1-3

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.

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: Not flammable.

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

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

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

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
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Vietnam OEL - TWAs 5 mg/m^3

Sodium chloride

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

Mepivacaine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m^3 to < 1000ug/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 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.)

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: 4.5-6.8
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Sodium chloride
No data available
HYDROCHLORIC ACID
No data available
SODIUM HYDROXIDE
No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Mepivacaine 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

Flammablity:
- **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 cause mild eye irritation. May cause slight skin irritation. (based on components) Anesthetic drug: may cause central nervous system and cardiovascular system effects
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

Mepivacaine Hydrochloride

11. TOXICOLOGICAL INFORMATION

Mouse Para-periosteal LD 50 117 mg/kg
Mouse Subcutaneous LD 50 260mg/kg
Rat Oral LD 50 > 5000mg/kg
Rat Intravenous LD 50 30mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride
Eye Irritation Rabbit Moderate
Skin 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: 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.

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

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

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

Mepivacaine Hydrochloride

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
EU EINECS/ELINCS List	217-023-9

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. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Revision date: 31-Jan-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

SAFETY DATA SHEET

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

Product Identifier

Material Name: Ceftriaxone for Injection (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Cephalosporin antibiotic

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

Intended Use: Pharmaceutical product used as antibiotic 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

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
May form combustible dust concentrations in air

Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory protection
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P362 - Take off contaminated clothing and wash before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations

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 require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	%
Ceftriaxone sodium	74578-69-1	277-930-0	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	100

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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 breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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

Ceftriaxone sodium

Pfizer Occupational Exposure Band (OEB): OEB 1 - Sensitizer (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

Exposure Controls

Engineering Controls: 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. Engineering controls should be used as the primary means to control exposures.

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.)

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:	Powder	**Color:**	White
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	C18-H18-N8-O7-S3.2Na	**Molecular Weight:**	661.60

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)
Ceftriaxone sodium
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

Flammablity:
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
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term: Inhalation of significant quantities of this substance could result in the health effects described in 'Known clinical effects'. Ingestion of this material can cause effects similar to those seen in clinical use including cholinergic crisis, characterized by severe nausea, vomiting, salivation, sweating, slow heart rate, low blood pressure, muscle weakness, respiratory depression.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Concomitant administration of aminoglycosides and cephalosporins has caused nephrotoxicity. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

Acute Toxicity: (Species, Route, End Point, Dose)

Ceftriaxone sodium

Rat Oral LD50 > 10 g/kg
Rat Subcutaneous LD50 > 5g/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)

Skin Irritation / Sensitization Hypersensitivity reactions, including cross reactions (with penicillins) and anaphylaxis, are common among the cephalosporins.

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

Ceftriaxone sodium

2 Generation Reproductive Toxicity Rat Intravenous586 mg/kg/day NOAEL No effects at maximum dose

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

Ceftriaxone sodium

11. TOXICOLOGICAL INFORMATION

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Micronucleus Mouse Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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.

15. REGULATORY INFORMATION

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

15. REGULATORY INFORMATION

Ceftriaxone sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	277-930-0

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	New data sheet.
Revision date:	28-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

Issuing Date January 5, 2015 **Revision Date** October 19, 2015 **Revision Number** 1

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

Product identifier

Product Name **Clorox® Clean-Up® Cleaner + Bleach$_1$ - Original**

Other means of identification

EPA Registration Number 5813-21

Recommended use of the chemical and restrictions on use

Recommended use Disinfecting bleach spray cleaner

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Address
The Clorox Company
1221 Broadway
Oakland, CA 94612

Phone: 1-510-271-7000

Emergency telephone number

Emergency Phone Numbers For Medical Emergencies, call: 1-800-446-1014
For Transportation Emergencies, call Chemtrec: 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Skin corrosion/irritation	Category 3
Serious eye damage/eye irritation	Category 2A

GHS Label elements, including precautionary statements

Emergency Overview

Signal word **Warning**

Hazard Statements
Causes mild skin irritation
Causes serious eye irritation

Appearance Clear, pale yellow **Physical State** Thin liquid **Odor** Citrus, herbaceous, bleach

Precautionary Statements - Prevention
Wash hands and any exposed skin thoroughly after handling.
Wear eye protection/face protection such as safety glasses.

Precautionary Statements - Response
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
If skin irritation occurs: Get medical advice/attention.

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
None

Hazards not otherwise classified (HNOC)
The following medical conditions may be aggravated by exposure to high concentrations of vapor or mist: heart conditions or chronic respiratory problems such as asthma, emphysema, or obstructive lung disease.

Unknown Toxicity
0.12% of the mixture consists of ingredient(s) of unknown toxicity

Other information
Toxic to aquatic life with long lasting effects

Interactions with Other Chemicals
Reacts with other household chemicals such as products containing ammonia, toilet bowl cleaners, rust removers, or acids to produce hazardous gases, such as chlorine and other chlorinated compounds.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade Secret
Sodium hypochlorite	7681-52-9	1 - 5	*
Sodium hydroxide	1310-73-2	0.1 - 1	*

* The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General Advice Show this safety data sheet to the doctor in attendance.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin Contact Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. If irritation develops, call a doctor.

Inhalation Move to fresh air. If breathing is affected, call a doctor.

Ingestion Call a poison control center or doctor immediately. Have person sip a glassful of water if able to swallow. DO NOT induce vomiting unless told to do so by a poison control center or doctor.

Protection of First-aiders Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Stinging and irritation of eyes.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Unsuitable Extinguishing Media
CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical
No information available.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with eyes, skin, and clothing. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental Precautions See Section 12 for ecological Information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Absorb and containerize. Wash residual down to sanitary sewer. Contact the sanitary treatment facility in advance to assure ability to process washed-down material.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Products containing ammonia, toilet bowl cleaners, rust removers, or acids.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hypochlorite 7681-52-9	None	None	None
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m^3	TWA: 2 mg/m^3	IDLH: 10 mg/m^3 Ceiling: 2 mg/m^3

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. NIOSH IDLH: Immediately Dangerous to Life or Health.

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection	If splashes are likely to occur: Wear safety glasses with side shields (or goggles). None required for consumer use.
Skin and Body Protection	Wear protective gloves and protective clothing.
Respiratory Protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene Measures	Remove and wash contaminated clothing before re-use. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical State	Thin liquid		
Appearance	Clear	**Odor**	Citrus, herbaceous, bleach
Color	Pale yellow	**Odor Threshold**	No information available

Property	**Values**	**Remarks/ Method**
pH	12.4 - 12.8	None known
Melting/freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	Not flammable	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
Upper flammability limit	No data available	None known
Lower flammability limit	No data available	None known
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	~1.03	None known
Water Solubility	Soluble in water	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive Properties	Not explosive	
Oxidizing Properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	No data available

10. STABILITY AND REACTIVITY

Reactivity
Reacts with other household chemicals such as products containing ammonia, toilet bowl cleaners, rust removers, or acids to produce hazardous gases, such as chlorine and other chlorinated compounds.

Chemical stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
None known based on information supplied.

Incompatible materials
Products containing ammonia, toilet bowl cleaners, rust removers, vinegar, or acids.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information .

Inhalation Exposure to vapor or mist may irritate respiratory tract.

Eye Contact May cause eye irritation.

Skin Contact Prolonged contact may cause irritation.

Ingestion Ingestion may cause irritation to mucous membranes and gastrointestinal tract, nausea, vomiting, and diarrhea.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hypochlorite 7681-52-9	8200 mg/kg (Rat)	>10000 mg/kg (Rabbit)	-
Sodium hydroxide 1310-73-2	-	1350 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms May cause redness and tearing of the eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Sodium hypochlorite 7681-52-9	-	Group 3	-	-

IARC (International Agency for Research on Cancer)
Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive Toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.
Chronic Toxicity Carcinogenic potential is unknown.
Target Organ Effects Respiratory system, eyes, skin, gastrointestinal tract (GI).

Aspiration Hazard No information available.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document
Not applicable.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Toxic to aquatic life with long lasting effects.

Persistence and Degradability
No information available.

Bioaccumulation
No information available.

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods
Dispose of in accordance with all applicable federal, state, and local regulations.

Contaminated Packaging
Do not reuse empty containers. Dispose of in accordance with all applicable federal, state, and local regulations.

14. TRANSPORT INFORMATION

DOT Not restricted.

TDG Not restricted for road or rail.

ICAO Not restricted, as per Special Provision A197, Environmentally Hazardous Substance exception.

IATA Not restricted, as per Special Provision A197, Environmentally Hazardous Substance exception.

IMDG/IMO Not restricted, as per IMDG Code 2.10.2.7, Marine Pollutant exception.

15. REGULATORY INFORMATION

Chemical Inventories

TSCA	All components of this product are either on the TSCA 8(b) Inventory or otherwise exempt from listing.
DSL/NDSL	All components are on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hypochlorite 7681-52-9	100 lb			X
Sodium hydroxide 1310-73-2	1000 lb			X

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium hypochlorite 7681-52-9	100 lb	-	RQ 100 lb final RQ RQ 45.4 kg final RQ
Sodium hydroxide 1310-73-2	1000 lb	-	RQ 1000 lb final RQ RQ 454 kg final RQ

EPA Statement
This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

> **WARNING: EYE AND SKIN IRRITANT**. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. For sensitive skin or prolonged use, wear gloves. Vapors may irritate. Avoid prolonged breathing of vapors. Use only in well ventilated areas. **Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease.**

US State Regulations

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

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Sodium hypochlorite 7681-52-9	X	X	X	X	
Sodium hydroxide 1310-73-2	X	X	X	X	

International Regulations

Canada
WHMIS Hazard Class
D2B - Toxic materials

16. OTHER INFORMATION

NFPA	**Health Hazard**	2	**Flammability** 0	**Instability** 0	**Physical and Chemical Hazards**	-
HMIS	**Health Hazard**	2	**Flammability** 0	**Physical Hazard** 0	**Personal Protection**	B

Prepared By
Product Stewardship
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Latham, NY 12110
1-800-572-6501

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Revision Note Revisions Sections 2, 8, and 14.

Reference 1086795/50546003.004

General Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Cyanocobalamin Injection, USP

WEST-WARD PHARMACEUTICALS

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.

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 LD50 Oral	Rabbit Rat	2000 mg/kg 1230 mg/kg	- -

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Benzyl alcohol	Skin - Mild irritant Skin - Moderate irritant Skin - Moderate irritant	Man Pig Rabbit	- - -	48 hours 16 mg 100 % 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 Inhalation (vapors)	82000 mg/kg 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.

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

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.

SANOFI PASTEUR

US - OSHA SAFETY DATA SHEET

Issue Date 24-Apr-2015 **Revision Date 22-Jan-2019** **Version 5**

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

Product identifier

Product Name DAPTACEL®

Other means of identification

Product Information Single-dose vial in packages of 10 vials

Synonyms Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Recommended use of the chemical and restrictions on use

Recommended Use Active immunization against diphtheria tetanus and pertussis as a five dose series in infants and children 6 weeks through 6 years of age.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address

Sanofi Pasteur
Discovery Drive
Swiftwater, PA 18370
Phone: 1-800-822-2463 (1-800-VACCINE)

Emergency telephone number

24 Hour Emergency Phone 1-703-741-5970 / 1-800-424-9300 CCN # 2118 (CHEMTREC)

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 throughout the sheet.

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance Uniform, white, cloudy suspension. **Physical state** Liquid **Odor** Not available.

Hazards not otherwise classified (HNOC)
Not classified as a hazardous substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Chemical Name	CAS No.	Weight-%
Diphtheria Toxoid Adsorbed	N/A	N/A
Tetanus Toxoid Adsorbed	N/A	N/A
Filamentous Haemagglutinin Adsorbed (FHA)	N/A	0.001
Fimbriae Types 2 and 3 Adsorbed (FIM)	N/A	0.001
Pertactin Adsorbed	N/A	0.0006
Pertussis Adsorbed	N/A	0.002
Water	7732-18-5	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 Common effects of the vaccine include the following: fussiness/irritability; inconsolable crying; decreased activity/lethargy; fever.

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.

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
Eye/face 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		
Appearance	Cloudy suspension.	**Odor**	Not available.
Color	White.	**Odor threshold**	Not available.

Property	Values	Remarks • Method
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
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 Common effects of the vaccine include the following: fussiness/irritability; inconsolable crying; decreased activity/lethargy; fever.

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	DAPTACEL vaccine has not been evaluated for mutagenic potential.
Carcinogenicity	DAPTACEL vaccine has not been evaluated for carcinogenic potential.
Reproductive toxicity	Human or animal data are not available to assess vaccine-associated risks in pregnancy.
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.

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

MEX Not regulated.

ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

RID Not regulated.

ADR Not regulated.

ADN 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
Component (Formaldehyde) is on Proposition 65 list; however, based on percentage of formulation it is not considered hazardous.

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.

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	24-Apr-2015
Revision Date	22-Jan-2019
Revision Note	Updated Sanofi Pasteur address; revised by Sanofi Pasteur

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

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

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

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 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
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 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

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. 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.

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

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)

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.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Epinephrine Injection (Hospira, Inc.)

Trade Name: Not applicable
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used for allergic reactions (anaphylaxis)

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

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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)	1.0
Sodium bisulfite	7631-90-5	231-548-0	Acute Tox. 4 (H302)	<2.0
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Sodium citrate	68-04-2	200-675-3	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 R phrases 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

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

Sodium bisulfite

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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm

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

Sodium chloride

Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Epinephrine

Pfizer Occupational Exposure Band (OEB): OEB 4 - Skin (control exposure to the range of 1ug/m^3 to <10ug/m^3, provide additional precautions to protect from skin contact)

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: Liquid
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
Solubility: Soluble: Water
pH: 2.2-5.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Epinephrine
No data available
Sodium bisulfite
No data available
Water for Injection
No data available
Sodium chloride
No data available
Sodium citrate
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
Specific Gravity:	~1
Viscosity:	No data available

Flammablity:

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. May be absorbed through mucous membranes and cause systemic effects.
Known Clinical Effects:	Adverse effects associated with therapeutic use include increased heart rate (tachycardia), palpitations, sweating, nausea, vomiting, difficulty breathing, dizziness, weakness, headache, anxiety, nervousness.

Acute Toxicity: (Species, Route, End Point, Dose)

Epinephrine
Rat Dermal LD50 62 mg/kg
Rat Oral LD50 30mg/kg

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, 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

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

Epinephrine
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Sister Chromatid Exchange Negative with activation
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Equivocal without activation

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.

Sodium bisulfite
IARC: Group 3 (Not Classifiable)

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties 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.

Additonal Information: The US Federal EPA waste listing for epinephrine does not include epinephrine salts. Disposal should be performed in accordance with all federal, state, and local regulatory requirements.

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

Sodium bisulfite

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	231-548-0

15. REGULATORY INFORMATION

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

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

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 citrate

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	200-675-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
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: Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: New data sheet.

Revision date: 03-Nov-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

Gebauer Company

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_2H_5Cl	**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 is 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 occasional 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 105ºF (41ºC). 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 120ºF (50ºC). 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 120ºF (50ºC). 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	**Korea ECL:**	Listed
Europe EINECS:	Listed	**Australia AICS:**	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: Ethyl Chloride is covered under the specific State regulations listed.	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 INFORMATOIN

This MSDS was revised and updated as of 04/23/2013 by Gebauer Company.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Furosemide Injection (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Not determined

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

Intended Use: Pharmaceutical active

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

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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

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	%
Furosemide	54-31-9	200-203-6	Repr. 2 (H361d)	1
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*

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

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

Hazardous Combustion Products: May include oxides of nitrogen and sulfur and products of chlorine

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

Avoid breathing vapor or mist. Avoid contact with eyes, skin 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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm

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

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Furosemide

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m^3 to < 100ug/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 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.)

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:**	No data available.
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: 9.0 (8.0-9.3)
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Furosemide
No data available
SODIUM HYDROXIDE
No data available
HYDROCHLORIC ACID
No data available
Water for Injection
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

Flammablity:
- **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: No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions
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
Short Term: Ingestion may cause lowering of blood pressure. Accidental or incidental ingestion of large amounts may cause nausea, abdominal discomfort, headache or dizziness. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Furosemide
Rat Oral LD 50 2600 mg/kg
Mouse Sub-tenon injection (eye) Minimum Symptomatic Dose 400mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

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

Furosemide
13 Week(s) Rat Oral 300 mg/kg LOAEL
13 Week(s) Mouse Oral 600 mg/kg LOAEL
6 Month(s) Dog Oral 10 mg/kg/day LOAEL
2 Year(s) Rat Oral 30 mg/kg/day LOAEL

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

Furosemide
Reproductive & Fertility Rat Oral 2.9 mg/kg/day LOAEL Fertility
Embryo / Fetal Development Rabbit Oral 25 mg/kg LOAEL Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development Rat Oral 12.5 mg/kg/day LOAEL Teratogenic
Embryo / Fetal Development Mouse Oral 1250 mg/kg/day LOAEL Fetotoxicity, Teratogenic

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

Furosemide
Bacterial Mutagenicity (Ames) Negative
In Vitro Micronucleus Human Lymphocytes Positive
Mammalian Cell Mutagenicity Mouse Lymphoma Positive

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Furosemide
2 Year(s) Male Rat Oral 15 mg/kg/day LOEL Tumors
104 Month(s) Female Mouse Oral 17.5 LOEL Tumors
2 Year(s) Female Rat Oral, in feed 700 ppm NOEL Not carcinogenic
104 Month(s) Male Mouse Oral, in feed 1400 ppm NOEL Not carcinogenic

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

Furosemide
IARC: Group 3 (Not Classifiable)

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated.

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.

This material is not regulated for transportation / carriage.

15. REGULATORY INFORMATION

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

Furosemide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present

15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-203-6

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

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

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
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: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: New data sheet.

Revision date: 31-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

Safety Data Sheet

Bristol-Myers Squibb Company

1. IDENTIFICATION		
Product Information		
Product name	KENALOG®-10 and 40 mg/ml (triamcinolone acetonide) Injectable Suspension	
Version	1.0, 24.02.2015	
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, Korea and Australia.	
Active substance	Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11.beta.,16.alpha.)-	
Synonyms	Sterile Triamcinolone Acetonide Suspension USP; Kenalog-10 Injection; Kenalog-40 Injection; Albicort; Kenacort	
Intended Uses	This material is a finished drug product for patient use. This material is used to provide relief of inflammatory and pruritic skin conditions.	
Company/Undertaking Identification		
Address	USA **Bristol-Myers Squibb Company** P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-800-332-2056	Ireland **Bristol-Myers Squibb Company** Swords Laboratories, Watery Lane Swords, Ireland MG-GBS-MSDS-Request@bms.com 353-1813-9456
Emergency Phone No.	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300 Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.	Ireland: 353-1813-9456

2. HAZARDS IDENTIFICATION	
Classification and Labelling Common to All Jurisdictions	
Classification	Toxic To Reproduction - Reproductive Toxicity - Category 1A Toxic To Reproduction - Developmental Toxicity - Category 1A Effects On Or Via Lactation
Symbol	
Signal Word	Danger
Hazard Statements	May damage fertility (male reproductive toxicity, female reproductive toxicity) . May damage the unborn child (developmental toxicity) . May cause harm to breast-fed children.
Precautionary	Do not breathe dust.

2. HAZARDS IDENTIFICATION	
Statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Use personal protective equipment as required.
Classification and Labelling for Specific Jurisdictions **USA**	
Classification	Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1
Hazard Statements	Causes damage to organs (adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin) through prolonged or repeated exposure.
Precautionary Statements	Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
EU	
Classification	Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 2
Hazard Statements	May cause damage to organs (adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin) through prolonged or repeated exposure.
UN	
Classification	Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1
Hazard Statements	Causes damage to organs (adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin) through prolonged or repeated exposure.
Precautionary Statements	Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS					
Components	Concentration	CAS No.	EU only		
			EC No./REACH Registration No.	Symbol(s)/ R-phrase(s)	H-code(s)
Hazardous components Triamcinolone Acetonide	1 - 4 %	76-25-5	200-948-7	T: R60, R61, R64, R66	H360F H360D H362 H372
Benzyl Alcohol	<= 1 %	100-51-6	202-859-9	Xn: R20/22	H302 H332

					H335
Other ingredients					
Non-Hazardous Ingredients	> 90 %	Not available	--	--	--
Other information: Sodium hydroxide and/or hydrochloric acid are used for pH adjustment. See section 16 for Symbol, R-phrase and H-code text.					

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	Medical conditions aggravated include: diabetes, liver disorders, infection, immunodeficiency, hypertension, myasthenia gravis, osteoporosis, peptic ulcer, psychotic disorders, colitis, kidney disorders. This product has been reported to interact with the following medications: diuretic, cyclosporine, immunosuppressants, NSAID (non-steroidal antiinflammatory drugs), drugs metabolized by cytochrome P-450, drugs that cause hyperglycemia, oral hypoglycemic drugs, neuromuscular blocking agents, fluoroquinoline antibiotics, certain vaccines, drugs that inhibit cytochrome P-450. 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: blood glucose test, a complete blood count with differential, a blood test for liver function, a blood test for kidney function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. 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	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Refer to HAZARDS IDENTIFICATION section for a description of hazards for this material. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), hydrogen halides Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
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). Clean area with detergent and water after spill pick-up, if appropriate. 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.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use. Store in spill containment pallet or other device to confine spills.
Storage Conditions	Store at room temperature. Protect against light. Keep away from heat, sparks and flames. Store locked up.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Triamcinolone Acetonide	1 µg/m3 8 hour-TWA (Skin)	--	--	--
Benzyl Alcohol		--	--	--
Sodium Hydroxide		2 mg/m3 Ceiling	--	--
Hydrochloric Acid		2 ppm Ceiling	5 ppm MAK 7.6 mg/m3 MAK 2 ppm TWA 3 mg/m3 TWA 4 ppm Peak 6 mg/m3 Peak 2 ppm MAK 3.0 mg/m3 MAK	5 ppm STEL 1 ppm TWA 2 mg/m3 TWA

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Benzyl Alcohol	Occupational Exposure Limits have been established by: - Czech Republic - Poland - Latvia
Sodium Hydroxide	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Czech Republic - Denmark - Estonia - Spain - Finland - France - Greece - Hungary - Ireland - Norway - Poland - Portugal - Sweden - Latvia
Hydrochloric Acid	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Czech Republic - Denmark - Estonia - Spain - Finland - France - Greece - Hungary - Ireland - Italy - The Netherlands - Norway - Poland - Portugal - Sweden - Latvia
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: 25 μg/m³.	
Engineering Controls and Ventilation	FOR MANUFACTURING PROCESSES (BULK): 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); and, approved vented enclosure. Quantities exceeding 1 kilogram should be handled in a designated laboratory using laminar flow/powder containment booth. 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 manufacturing and pilot plant operations, use direct coupling and closed transfer systems for all bulk transfers. Use dust tight valves as appropriate. HEPA filtration of local exhaust ventilation (LEV) is required. 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.
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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
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 (EN 420, EN 374). If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat(EN 340)or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability.
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance	
Physical State	liquid
Color	white to off-white
Form	suspension
Odour	
Odour	Not remarkable.
Odor Threshold	Not available
pH	5 - 7
Other information	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coefficient [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	1.015
Viscosity, dynamic	similar to water
Viscosity, kinematic	Not available
% Volatile	Not available

9. PHYSICAL AND CHEMICAL PROPERTIES

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	0 °C
Oxidizing Potential	Not available

Vapor Properties

Vapor Density	(Air =1): If adequate temperatures caused material to volatize, its vapor density would be much greater than 1. (Heavier than air)
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
Materials to avoid	Not available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), hydrogen halides
Hazardous reactions	Not available

Sensitivity to static discharge/Dust exp.

Summary Statements	not applicable

11. TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, inhalation, Eye contact, Skin contact
Eye Irritation	Triamcinolone Acetonide Mildly and/or transiently irritating to eyes Benzyl Alcohol Irritating to eyes.
Skin Irritation	Triamcinolone Acetonide

11. TOXICOLOGICAL INFORMATION	
	Repeated exposure may cause skin dryness or cracking. skin thinning Benzyl Alcohol Mildly irritating to skin
Respiratory Irritation	Triamcinolone Acetonide May cause irritation of respiratory tract. Benzyl Alcohol Irritating to respiratory tract.
Sensitization	Triamcinolone Acetonide Not a dermal sensitizer Allergic contact dermatitis is quite rare but has been reported. Benzyl Alcohol Several studies were conducted. The results were negative and positive. Only rare mild cutaneous sensitization reactions have been observed in adults.
Acute Toxicity Study	**Acute Oral** Triamcinolone Acetonide LD50 (mouse): 5,000 mg/kg Benzyl Alcohol LD50 (rat): 1,230 mg/kg LD50 (mouse): 1,360 mg/kg LD50 (rabbit): 1,040 mg/kg LD50 (guinea pig): 2,500 mg/kg **Acute Dermal** Benzyl Alcohol LD50 (rabbit): 2,000 mg/kg **Acute inhalation toxicity** Benzyl Alcohol LC50 (rat): 8.8 mg/l/4 H **Acute toxicity (other routes of administration)** Triamcinolone Acetonide LD50 (rat, subcutaneous): 13.1 mg/kg LD50 (mouse, subcutaneous): 132 mg/kg LD50 (mouse, intraperitoneal): 105 mg/kg
Repeated Dose Toxicity	Benzyl Alcohol 16 D - 24 months oral (daily) rat, mouse study (males and females): LOAEL = 200 mg/kg; High dose effects include: irregular respiration, lethargy, abnormal gait, decreased weight gain, mortality. High dose microscopic effects include: kidney, brain, muscle, thymus.

11. TOXICOLOGICAL INFORMATION

Genetic Toxicity	Triamcinolone Acetonide **In vitro** Ames reverse-mutation assay -- negative Forward gene mutation assay -- negative **Mutagenicity Assessment** Several studies were conducted. The weight of evidence demonstrates that this material is not genotoxic. Benzyl Alcohol **Mutagenicity Assessment** The weight of evidence demonstrates that this material is not genotoxic.
Carcinogenicity	Triamcinolone Acetonide 2 years oral (daily) rat study : Tumor NOAEL = 0.001 mg/kg No treatment-related tumors were observed. 2 years oral (daily) mouse study : Tumor NOAEL = 0.003 mg/kg No treatment-related tumors were observed. 2 years drinking water (daily) rat study : Tumor LOAEL = 0.0048 mg/kg [tumor organs: liver] **Carcinogenicity Assessment** Not classifiable as to its carcinogenicity to humans. Benzyl Alcohol 2 Years oral (5/week) rat study : Tumor NOAEL = 400 mg/kg (males and females). No treatment-related tumors were observed. 2 Years oral (5/week) mouse study : Tumor NOAEL = 200 mg/kg (males and females). No treatment-related tumors were observed. **Carcinogenicity Assessment** This material did not show carcinogenic potential in animal studies.

Carcinogenicity	**ACGIH**	**IARC**	**NTP**
Triamcinolone Acetonide	--	--	--
Benzyl Alcohol	--	--	--

Reproductive Toxicity	Triamcinolone Acetonide **Assessment Reproductive Toxicity** Several studies were conducted. May impair fertility. Maternal effects include: menstrual irregularities . Paternal effects include: sperm abnormalities See "Human Experience". See also "Developmental Toxicity" for information on reproductive effects.
Developmental Toxicity	Triamcinolone Acetonide **Developmental Toxicity Assessment** Several developmental studies were conducted. Birth defects were observed in animal studies. Compound may be toxic during early embryonic development. Teratogen This compound and/or its metabolites may be excreted into the milk. May cause harm to breastfed babies.

11. TOXICOLOGICAL INFORMATION	
	Benzyl Alcohol **Developmental Toxicity Assessment** Limited data are available.
Human experience	**Experiences with Human Exposure** Triamcinolone Acetonide General effects therapeutic use low exposure - acute effects include: muscle weakness, muscle pain, bone fractures, infection, oedema, headache, difficulty sleeping, vertigo, restlessness, euphoria, mental disturbance, depression, anxiety, mood changes, seizure disorders, nosebleeds, cough, fever, nausea, anaphylaxis, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, allergic reactions, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling, increase in blood pressure, Cushing's syndrome, electrolyte disturbance, hyperglycemia, adrenocortical insufficiency, withdrawal symptoms, osteoporosis, bone effects, menstrual irregularities, impaired spermatogenesis, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychiatric disorders, pancreatitis, changes in white blood cell parameters, alopecia, asthma, growth retardation, skin effects, injection site reactions, cardiac disorders, death. Benzyl Alcohol See also symptoms below.
Target Organs	Triamcinolone Acetonide adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, male reproductive organs Benzyl Alcohol central nervous system
Symptoms	Triamcinolone Acetonide See "Human Experience". Benzyl Alcohol nausea, vomiting, diarrhoea, CNS depression, dizziness, headache, vision changes, rash, redness and swelling of skin, vertigo, delirium
Pharmacokinetics/ Toxicokinetics	Triamcinolone Acetonide Absorption: Not available Distribution: Not available Metabolism: Not available Elimination: Half-life = 2 - 3 Hour(s) (Human).

11. TOXICOLOGICAL INFORMATION

Other Toxicity Information	Not available
Other Information:	This SDS may contain toxicological and/or pharmacological information derived from either the specified product or from compounds in the same pharmacological class.

12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Acute Toxicity to Fish

Benzyl Alcohol

LC50 (Pimephales promelas, 96 H): 460 mg/l.

LC50 (Lepomis macrochirus, 96 H): 10 mg/l.

Acute Toxicity to Aquatic Invertebrates

Triamcinolone Acetonide

EC50 (Daphnia magna (Water flea), 48 H): > 100 mg/l.

Benzyl Alcohol

EC50 (water flea, 48 H): 23 mg/l.

Toxicity to aquatic plants

Benzyl Alcohol

EC50 (Anabaena variabilis, 3 H): 35 mg/l

Toxicity to microorganisms

Benzyl Alcohol

EC50 (Photobacterium phosphoreum, 30 Minute): 71.4 mg/l

Mobility Not available

Persistence and degradability

Biodegradation

Triamcinolone Acetonide

Ultimate aerobic biodegradation (28 D): 3 %; Not Readily Biodegradable - unlikely to undergo rapid biodegradation in the environment

Benzyl Alcohol

Ready biodegradation (30 D): > 90 %; Readily biodegradable - rapidly biodegrades in the environment

Summary Statements

Chemical Fate

KENALOG®-10 and 40 mg/ml (triamcinolone acetonide) Injectable Suspension

Not readily biodegradable.

PBT and vPvB assessment 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. REGULATORY INFORMATION

United States of America

313 Toxic Release Inventory	No components listed on the SARA 313 inventory.
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.

EU Directive 1999/45/EC

BULK MATERIAL

Symbol(s)	T: Toxic
R-phrase(s)	R60: May impair fertility. R61: May cause harm to the unborn child. R64: May cause harm to breastfed babies.
S-phrase(s)	S23: Do not breathe gas/fumes/vapour/spray. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S38: In case of insufficient ventilation, wear suitable respiratory equipment. S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible). S53: Avoid exposure - obtain special instructions before use.

DRUG PRODUCT

Classification	Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

Regulatory Authorizations and Restrictions:	Not available

16. OTHER INFORMATION

Text of Symbol(s), R-phrase(s) and H-code(s) mentioned in Section 3

H302	Harmful if swallowed.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H360D	May damage the unborn child
H360F	May damage fertility
H362	May cause harm to breast-fed children.
H372	Causes damage to organs through prolonged or repeated exposure.
R20/22	Harmful by inhalation and if swallowed.
R60	May impair fertility.
R61	May cause harm to the unborn child.
R64	May cause harm to breastfed babies.
R66	Repeated exposure may cause skin dryness or cracking.
T	Toxic
Xn	Harmful

Recommended Restrictions for Use:

Not available

SDS preparation information

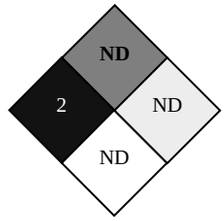
Prepared by	Research and Development Environment, Health and Safety 1-732-227-7380
Prepared on	24.02.2015 DD/MM/YYYY
	This Safety Data Sheet was reformatted in accordance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN).
Other information	

HMIS

Health	2*
Flammability	Not Determined (ND)
Reactivity	Not Determined (ND)
Personal protective equipment	See Section 8.

NFPA

Health	2
Fire	ND
Reactivity	ND
Special	ND



Country- Specific Emergency Phone Numbers

CHEMTREC In-Country Dial Numbers	Local # Provided in Country	Toll Free in Country*	Greeting Language
CHEMTREC South Africa*		0-800 983-611	English
CHEMTREC Argentina (Buenos Aires)	+(54)-1159839431		Latin American Spanish
CHEMTREC Brazil (Rio De Janeiro)	+(55)-2139581449		Portuguese
CHEMTREC Chile (Santiago)	+(56)-25814934		Latin American Spanish
CHEMTREC Colombia *		01800-710-2151	Latin American Spanish
CHEMTREC Mexico*		01-800-681-9531	Latin American Spanish
CHEMTREC Peru (Lima)	+(51)-17071295		Latin American Spanish
CHEMTREC China*	4001-204937		Mandarin
CHEMTREC Hong Kong (Hong Kong)*		800-968-793	Cantonese
CHEMTREC India *		000-800-100-7141	Hindi
CHEMTREC Indonesia*		001-803-017-9114	Indonesian
CHEMTREC Japan (Tokyo)	+(81)-345209637		Japanese
CHEMTREC Malaysia *		1-800-815-308	Malay
CHEMTREC Philippines *		1-800-1-116-1020	Tagalog
CHEMTREC Singapore*		800-101-2201	Mandarin
CHEMTREC Singapore	+(65)-31581349		Mandarin
CHEMTREC South Korea*		00-308-13-2549	Korean
CHEMTREC Taiwan*		00801-14-8954	Mandarin
CHEMTREC Thailand *		001-800-13-203-9987	Thai
CHEMTREC Vietnam (Ho Chi Minh City)	+(84)-838012436		Vietnamese
CHEMTREC Australia (Sydney)	+(61)-280372594		English
CHEMTREC Belgium (Brussels)	+(32)-28083237		French and Flemish
CHEMTREC Czech Republic (Prague)	+(420)-228880039		Czech
CHEMTREC France	+(33)-975181407		French
CHEMTREC Germany *		0800-181-7059	German
CHEMTREC Hungary (Bodapest)	+(36)-18088425		Hungarian
CHEMTREC Italy *		800-789-767	Italian
CHEMTREC Italy (Milan)	+(39)-0245557031		Italian
CHEMTREC Netherlands	+(31)-858880596		Dutch
CHEMTREC Poland (Warsaw)	+(48)-223988029		Polish
CHEMTREC Spain*		900-868538	European Spanish
CHEMTREC Sweden (Stockholm)	+(46)-852503403		Swedish
CHEMTREC Switzerland (Zurich)	+(41)-435016715		German
CHEMTREC UK (London)	+(44)-870-8200418		English
CHEMTREC Bahrain (Bahrain)	+(973)-16199372		Arabic
CHEMTREC Israel (Tel Aviv)	+(972)-37630639		Hebrew
*Phone numbers for countries marked with an asterisk must be dialed within the country			

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.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Ketorolac Tromethamine Injection, USP (Hospira Inc.)

Trade Name: Not established
Synonyms: Ketorolac trometamol
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

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

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

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

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

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
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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

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 require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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	%
Ketorolac tromethamine	74103-07-4	Not Listed	Acute Tox.3 (H301) STOT RE 2 (H373) Repr.1A (H360D)	1.5-3.0
Ethanol	64-17-5	200-578-6	Flam. Liq. 2 (H225)	7 - 12
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**

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.

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: Use carbon dioxide, dry chemical, or water spray.

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 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 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 product used as non-steroidal, anti-inflammatory drug (nsaid)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Ethanol

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm 1880 mg/m^3
Austria OEL - MAKs	1000 ppm 1900 mg/m^3
Belgium OEL - TWA	1000 ppm 1907 mg/m^3
Bulgaria OEL - TWA	1000 mg/m^3
Czech Republic OEL - TWA	1000 mg/m^3
Denmark OEL - TWA	1000 ppm 1900 mg/m^3
Estonia OEL - TWA	500 ppm 1000 mg/m^3
Finland OEL - TWA	1000 ppm 1900 mg/m^3
France OEL - TWA	1000 ppm 1900 mg/m^3
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m^3
Germany (DFG) - MAK	500 ppm 960 mg/m^3
Greece OEL - TWA	1000 ppm 1900 mg/m^3
Hungary OEL - TWA	1900 mg/m^3
Latvia OEL - TWA	1000 mg/m^3
Lithuania OEL - TWA	500 ppm 1000 mg/m^3
Netherlands OEL - TWA	260 mg/m^3
OSHA - Final PELS - TWAs:	1000 ppm 1900 mg/m^3
Poland OEL - TWA	1900 mg/m^3
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m^3
Russia OEL - TWA	1000 mg/m^3
Slovakia OEL - TWA	500 ppm 960 mg/m^3
Slovenia OEL - TWA	1000 ppm 1900 mg/m^3
Sweden OEL - TWAs	500 ppm 1000 mg/m^3
Switzerland OEL -TWAs	500 ppm 960 mg/m^3
Vietnam OEL - TWAs	1000 mg/m^3

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm

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

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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).
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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	Clear to light yellow
Odor:	Alcohol Slight	**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:	6.9-7.9
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
Sodium chloride
No data available
Ketorolac tromethamine
No data available
Ethanol
No data available
Water for injection
No data available
Hydrochloric Acid
No data available
Sodium hydroxide
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
Specific Gravity: 0.991
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** 55 (ethanol)
- **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 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
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Ingestion of this material may cause effects similar to those seen in clinical use including serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Clinical use of this drug has caused headache, dizziness, blurred vision, ringing of the ears, skin rash, itching, swelling, and liver effects.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Ketorolac tromethamine
Rat Oral LD50 189 mg/kg
Mouse Oral LD50 293mg/kg

Ethanol
Mouse Oral LD50 3,450 g/m^3
Rat Oral LD50 7,060mg/kg
Mouse Inhalation LC50 4h 39g/m^3
Rat Inhalation LC50 10h 20,000ppm

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Ethanol
Eye Irritation Rabbit Severe

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Ketorolac tromethamine
Reproductive & Fertility-Females Rat Oral16 mg/kg/day NOAEL Negative
Reproductive & Fertility-Males Rat Oral 9 mg/kg/day NOAEL Negative
Prenatal & Postnatal Development Rabbit Oral 3.6 mg/kg/day NOAEL Negative
Prenatal & Postnatal Development Rat Oral 10 mg/kg/day NOAEL Negative

11. TOXICOLOGICAL INFORMATION

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

Ketorolac tromethamine
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Unscheduled DNA Synthesis Not specified Negative
In Vivo Micronucleus Mouse Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ketorolac tromethamine
24 Month(s) Rat Oral 5 mg/kg/day NOAEL Not carcinogenic
18 Month(s) Mouse Oral 2 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. See below

Ethanol
IARC: Group 1 (Carcinogenic to Humans)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

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

Ethanol
Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L
Oncorhynchus mykiss (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L
Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14,200 mg/L

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.

15. REGULATORY INFORMATION

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

Ketorolac tromethamine

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

Ethanol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

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

15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-595-7

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances	1000 lb
and their Reportable Quantities:	454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	215-185-5

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
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, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Revision date: 03-Aug-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

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

Product Identifier

Material Name: Lidocaine Hydrochloride Injection (Hospira, Inc.)

Trade Name: Lignocaine Injection
Synonyms: Lidocaine
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

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lidocaine Hydrochloride	73-78-9	200-803-8	Acute Tox.4 (H302)	1-2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
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: * 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.

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

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
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Lidocaine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m^3 to < 1000ug/m^3)

Sodium chloride

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/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 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.)

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: 5-7
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Lidocaine Hydrochloride
No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Water for injection
No data available
Sodium chloride
No data available
HYDROCHLORIC ACID
No data available
SODIUM HYDROXIDE
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

Flammablity:
- **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: 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)

Lidocaine Hydrochloride

11. TOXICOLOGICAL INFORMATION

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

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Lidocaine Hydrochloride
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

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)

Lidocaine Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Negative

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: 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.

15. REGULATORY INFORMATION

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

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

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
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
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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; 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. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.
Revision date:	26-Jul-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

SAFETY DATA SHEET

Product Name: **MARCAINE - Bupivacaine Hydrochloride Injection**

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	MARCAINE - Bupivacaine Hydrochloride Injection
Synonyms	2-Piperidinecarboxamide, 1-butyl-*N*-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate

2. HAZARD(S) IDENTIFICATION

Emergency Overview

MARCAINE - Bupivacaine Hydrochloride Injection is a solution containing bupivacaine hydrochloride, a local anesthetic used for pain management. In clinical use, this material is indicated for local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract. Based on clinical use, possible target organs include the nervous system, respiratory system, and cardiovascular system.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA
Precautionary Statement(s) Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Bupivacaine Hydrochloride Monohydrate
Chemical Formula $C_{18}H_{28}N_2O \bullet HCl \bullet H_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Bupivacaine Hydrochloride Monohydrate	≤ 0.75	14252-80-3	TK6125000

Non-hazardous ingredients include Water for Injection and may include dextrose. Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are used to adjust the pH. Multiple-dose vials contain 0.1% of methylparaben added as preservative.

4. 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.

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required for hazard control under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Bupivacaine Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Skin Protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Eye Protection	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Engineering Controls	Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless liquid
Odor	Not determined
Odor Threshold	NA
pH	Between 4 and 6.5
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Bupivacaine hydrochloride monohydrate is a white crystalline powder that is freely soluble in 95 percent ethanol, soluble in water, and slightly soluble in chloroform or acetone
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Strongly alkaline conditions. Methyl vinyl ether; zinc.
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Bupivacaine Hydrochloride	100	LD50	Oral	18	mg/kg	Rabbit
Bupivacaine Hydrochloride	100	LD50	Intravenous	6 6.1 3.4	mg/kg mg/kg mg/kg	Rat Mouse Rabbit

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Published reports have indicated that similar local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

11. TOXICOLOGICAL INFORMATION: continued

Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product.
Reproductive Effects	None anticipated from normal handling of this product. Decreased pup survival in rats and an embryocidal effect in rabbits have been observed when bupivacaine hydrochloride was administered to these species in doses comparable to nine and five times respectively the maximum recommended daily human dose (400 mg).
Mutagenicity	The mutagenic potential of this product has not been evaluated.
Carcinogenicity	Long-term studies in animals to evaluate the carcinogenic potential of most local anesthetics, including bupivacaine, have not been conducted.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the nervous system, respiratory system, and cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal of all wastes should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention 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.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator:	Hospira GEHS
Date Prepared:	October 17, 2012
Date Revised:	June 02, 2014

Disclaimer:
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SDS DATE: 10/29/15

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Hydrogen Peroxide, 3%
MFR #: 23-A0013, 23-D0012, 23-F0010

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company)
Day or night

PRODUCT DESCRIPTION: McKesson Hydrogen Peroxide, 3%

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: N/A

POTENTIAL HEALTH EFFECTS:

EYES: Eye Dam. 1;H318 Causes serious eye damage.

SKIN: Skin Corr. 1B;H314 Causes severe skin burns and eye damage.

INGESTION: N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY
OSHA: TWA 1 ppm (1.4mg/m3) **ACGIH:** TWA: 1ppm **NTP:** N/A **IARC:** N/A
OTHER: NIOSH: TWA 1ppm (1.4mg/m3)

SECTION 2 NOTES:

CAS No.	Ingredient	Source	Value
0007722-84-1	Hydrogen peroxide	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group **2b:** No; Group 3: Yes; Group 4: No;

Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.
001 - Hydrogen Peroxide 3% USP

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

[Prevention]:

P260 Do not breathe mist / vapors / spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

[Response]:

P301+330+331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Stay at rest.

P303+361+353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.

P304+340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.

P310 Immediately call a POISON CENTER or doctor / physician.

P363 Wash contaminated clothing before reuse.

[Storage]:

P405 Store locked up.

[Disposal]:

P501 Dispose of contents / container in accordance with local / national regulations.

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits

SECTION 3 NOTES:

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Hydrogen peroxide **CAS Number: 0007722-84-1**	**1.0 - 10**	**Ox. Liq. 1;H271** **Acute Tox. 4;H332** **Acute Tox. 4;H302** **Skin Corr. 1A;H314**	**[1][2]**

Substance classified with a health or environmental hazard.
Substance with a workplace exposure limit.
PBT-substance or vPVP-substance.
*The full text of the phrases are shown in Section 16.

SECTION 4: FIRST-AID MEASURES

EYES: Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

SKIN: Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

INGESTION: If swallowed do NOT induce vomiting and obtain immediate medical attention.

INHALATION: Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration.

If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Overview	Inhalation of vapors and mists irritate the nose and throat. Minimally irritating to the eyes and mildly irritating to the skin. See section 2 for further details.
Eyes	Causes serious eye damage.
Skin	Causes severe skin burns and eye damage.

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: N/A
(% BY VOLUME) LOWER: N/A

FLASH POINT: N/A
METHOD USED: N/A

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

HEALTH:	N/A	**FLAMMABILITY:**	N/A	**REACTIVITY:**	N/A	**OTHER:**	N/A

HMIS HAZARD CLASSIFICATION

HEALTH:	N/A	**FLAMMABILITY:**	N/A	**REACTIVITY:**	N/A	**PERSONAL:**	N/A

EXTINGUISHING MEDIA: Recommended extinguishing media: flood with water spray or water fog.

SPECIAL FIRE FIGHTING PROCEDURES: Do not breathe mist/vapors/spray.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: Oxygen which supports combustion.

SECTION 5 NOTES: Firefighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: N/A

SECTION 6 NOTES:
Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

Environmental precautions

Biodegradable, non-hazardous to environment.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing before reuse.

Methods and material for containment and cleaning up.

Flush with water: wear fubber boots, rubber apron and goggles.

SECTION 7: HANDLING AND STORAGE

HANDLING: See section 2 for further details. - [Prevention]:

STORAGE: Handle containers carefully to prevent damage and spillage.

Incompatible materials: Reducing agents, combustible materials.

Store in a cool, dark place. Avoid extreme heat.

See section 2 for further details. - [Storage]:

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: N/A

VENTILATION:

RESPIRATORY PROTECTION: If workers are exposed to concentrations above the exposure limit they must use the appropriate, certified respirators.

EYE PROTECTION: Protective goggles if desired.

SKIN PROTECTION: Rubber or vinyl gloves.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove solied clothing and wash thoroughly before reuse.

EXPOSURE GUIDELINES:

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Clear, colorless, odorless liquid

PHYSICAL STATE: N/A

pH AS SUPPLIED: N/A
pH (Other): N/A
BOILING POINT: 212°F
MELTING POINT: N/A
FREEZING POINT: N/A
VAPOR PRESSURE (mmHg): 23
@ N/A
DENSITY (lb/gal): N/A
@ N/A
SPECIFIC GRAVITY (H2O = 1): 1.1

@ N/A
EVAPORATION RATE: >1

BASIS (=1): N/A

SOLUBILITY IN WATER: Complete

PERCENT SOLIDS BY WEIGHT: N/A

PERCENT VOLATILE: N/A
BY WT/ N/A **BY VOL @** N/A

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

WITH WATER: N/A **LBS/GAL**
WITHOUT WATER: N/A **LBS/GAL**

MOLECULAR WEIGHT: N/A

VISCOSITY: N/A

SECTION 9 NOTES:
Heavy Metals: 5 ppm maximum
Limit of Preservative: NMT 50 mg
Hydrogen Peroxide Assay: 2.5-3.5%

SECTION 10: STABILITY AND REACTIVITY

STABLE **UNSTABLE**

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID (STABILITY): Extreme heat and combustion.

INCOMPATIBILITY (MATERIAL TO AVOID): Reducing agents, combustible materials.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Oxygen, which supports combustion.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Acute Toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LD50, mg/L/4hr	Inhalation Dust/Mist LD50, mg/L/4hr	Inhalation Gas LD50, ppm
Hydrogen peroxide - (7722-84-1)	801.00, Rat - Category: 4	2,000.00, Rat - Category: 4	2.00, Rat - Category: 2	No data available	No data available

Note: When no toute specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	1B	Causes severe skin burns and eye damage.
Serious eye damage/irritation	1	Causes serious eye damage.
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

Toxicity : No additional information provided for this product. See section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Hydrogen peroxide - (7722-84-1)	22.00, Oncorhynchus mykiss	**2.32,** Daphnia magna	0.71 (72 hr), Microcystis pulverea **ssp.** incerta

Persistence and degradability

There is no data available on the preparation itself.

Bioaccumulative potential

Not Measured

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

Other adverse effects

No data available.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Observe all federal, state and local regulations when disposing of this substance.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: Not regulated.
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
DOT SHIPPING ID NUMBER: N/A
DOT PACKING GROUP: N/A
DOT HAZARD CLASS: N/A
DOT LABEL STATEMENT: N/A

WATER TRANSPORTATION
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

AIR TRANSPORTATION
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): All components of this material are either listed or exempt from listing on the TSCA

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A

EPCRA 301 Extremely Dangerous: Hydrogen Peroxide

SARA 311/312 HAZARD CATEGORIES: To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

SARA 313 REPORTABLE INGREDIENTS: Contains NO hazardous ingredients subject to reporting requirements of Section 313 of SARA Title II.

STATE REGULATIONS:

New Jersey RTK Substances (>1%):

Hydrogen peroxide

Pennsylvania RTK Substances (>1%):

Hydrogen peroxide

Proposition 65 - Carcinogens (>0.0%):
No chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

No chemicals at levels which require reporting under this statute.

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

SDS DATE: 8/7/2015

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Isopropyl Rubbing Alcohol 70%
MFR #: 23-D0022, 23-D0024

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: Alcohol, Isopropyl 70%

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: N/A

POTENTIAL HEALTH EFFECTS: N/A

EYES: N/A

SKIN: N/A

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:	No	**ACGIH:**	N/A	**NTP:**	No	**IARC:**	Group 1: No, Group 2a: No, Group 2b: No, Group 3: Yes, Group 4: No

OTHER: N/A

SECTION 2 NOTES:

Classification of the substance or mixture
Flam. Liq. 3;H226 Flammable liquid and vapor.
Eye Irrit. 2;H319 Causes serious eye irritation.
STOT SE 3;H336 May cause drowsiness or dizziness.

Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

Warning
H226 Flammable liquid and vapor.
H319 Causes serious eye irritation.
H336 May cause drowsiness and dizziness.

Prevention
P210 Keep away from heat / sparks / open flames / hot surfaces - No smoking.
P235 Keep cool.
P240 Ground / bond container and receiving equipment.
P241 Use explosion-proof electrical / ventilating / light / equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust / fume / gas / mist / vapors / spray.
P264 Wash thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves / eye protection / face protection.

Response
P303+361+353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+312 IF INHALED: Call a POISON CENTER or doctor / physician if you feel unwell.
P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P337+313 If eye irritation persists: Get medical advice / attention.
P340 Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P370+378 In case of fire: Use extinguishing media listed in section 5 of SDS for extinction.

Storage
P403+233 Store in a well ventilated place. Keep container tightly closed.
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
Isopropyl Alcohol	67-63-0	50-75	OSHA TWA 400 ppm (980mg/m3)STEL 500 ppm ACGIH TWA: 200 ppm STEL: 400 ppm Revised 2003, NIOSH TWA 400 ppm (980 mg/m3) ST 500 ppm (1225 mg/m3)

SECTION 3 NOTES:

GHS Classification:
Flam. Liq. 2;H225
Eye Irrit. 2;H319
STOT SE 3;H336

Substance classified with a health or environmental hazard.

Substance with a workplace exposure limit.
PBT-substance or vPvB-substance.

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 obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

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:

SECTION 4 NOTES: N

General: 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 Signs and Symptoms of Exposure: Giddiness, headache, dizziness and nausea.

Medical Conditions Generally Aggravated by Exposure: Pre-existing and respiratory disorders, may be aggravated by exposure.

Health Hazards (Acute and Chronic): Generally used as a rubdown. Vapor irritates eyes.

High concentration of vapor can irritate respiratory tract, is anesthetic and may cause CNS depression.

Not a carcinogen.

Exposure to solvent vapor concentrations from the component solvents in excess of the stated occupational exposure limits may result in adverse health effects such as mucous membrane and respiratory system irritation and adverse effects on the kidneys, liver and central nervous system. Symptoms include headache, nausea, dizziness, fatigue, muscular weakness, drowsiness and in extreme cases, loss of consciousness.

Repeated or prolonged contact with the preparation may cause removal of natural fat from the skin resulting in dryness, irritation and possible non-allergic contact dermatitis. Solvents may also be absorbed through the skin. Splashes of liquid in the eyes may cause irritation and soreness with possible reversible damage. See section 2 for further details.

Inhalation May cause drowsiness or dizziness.

Eyes Causes serious eye irritation.

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: 12
(% BY VOLUME) LOWER: 2

FLASH POINT: 77 F
METHOD USED: TCC

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

HEALTH:	N/A	FLAMMABILITY:	N/A	REACTIVITY:	N/A	OTHER:	N/A

HMIS HAZARD CLASSIFICATION

EXTINGUISHING MEDIA:
Recommended extinguishing media; alcohol resistant foam, CO2, water fog.
Do not use; water jet.

SPECIAL FIRE FIGHTING PROCEDURES:

UNUSUAL FIRE AND EXPLOSION HAZARDS:

HAZARDOUS DECOMPOSITION PRODUCTS:

SECTION 5 NOTES:

Special hazards arising from the substance or mixture
Hazardous decomposition: Burning may produce carbon monoxide and carbon dioxide contamination.
Keep away from heat / sparks / open flames / hot surfaces - No smoking.
Avoid breathing dust / fume / gas / mist / vapors / spray.

Advice for fire-fighters
Dilution of burning liquid with water will affect extinguishment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

SECTION 6 NOTES:

Personal precautions, protective equipment and emergency procedures
Put on appropriate personal protective equipment (see section 8).

Environmental precautions
Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

Methods and material for containment and cleaning up
Eliminate all sources of ignition. Small spills should be flushed with large quantities of water, larger spills should be collected for disposal. Atomize into an incinerator where permitted under appropriate federal, state, and local regulations.

SECTION 7: HANDLING AND STORAGE

HANDLING: Do NOT take internally. Flammable liquid. Keep away from heat, sparks and open flames. Keep container closed.

STORAGE: Handle containers carefully to prevent damage and spillage. Naked flames and smoking should not be permitted in storage areas. It is recommended that fork lift trucks and electrical equipment are protected to the appropriate standard.Incompatible materials: Anyhydride, isocyanate, monomer and organo-metallic.

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:
Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

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 if desired.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES:
Ensure showers and eyewash stations are available. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiledclothing and wash thoroughly before reuse.

EXPOSURE GUIDELINES: N/A

SECTION 8 NOTES:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Colorless Liquid, Characteristic

PHYSICAL STATE:

pH AS SUPPLIED: Not Measured
pH (Other): N/A
BOILING POINT: 87°F
MELTING POINT: Not Measured
FREEZING POINT: Not Measured
VAPOR PRESSURE (mmHg): 33
@ N/A
DENSITY (lb/gal): 2.07
@ N/A
SPECIFIC GRAVITY (H2O = 1): 0.88
@ N/A
EVAPORATION RATE: 2.3

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: Not Measured

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE **UNSTABLE**

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID (STABILITY): Avoid hheat, sparks and open flame.

INCOMPATIBILITY (MATERIAL TO AVOID): Anhydride, isocyanate, monomer and organo-metallic

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Burning may product carbon monoxide and carbon dioxide contamination.

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES:
Reactivity
Hazardous Polymerization will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:
Acute toxicity
Repeated or prolonged contact with the preparation may cause removal of natural fat from the skin resulting in dryness, irritation and possible non-allergic contact dermatitis. Solvents may also be absorbed through the skin. Splashes of liquid in the eyes may cause irritation and soreness with possible reversible damage.

Ingredient Isopropyl Alcohol (67-63-0)	Oral LD50 mg/kg , 4,710.00, Rat – Category 5 Skin LD50 mg/kg, 12,800.00, Rat – Category N/A Inhalation Vapor mg/l/4hr, 72.60, Rat – Category N/A Inhalation Dust/Mist LD50 mg/l/4h – No data available Inhalation Gas LD50 ppm – No data available

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).

Classification Category Hazard Description
Acute toxicity (oral) --- Not Applicable
Acute toxicity (dermal) --- Not Applicable
Acute toxicity (inhalation) --- Not Applicable
Skin corrosion/irritation --- Not Applicable
Serious eye damage/irritation 2 Causes serious eye irritation.
Respiratory sensitization --- Not Applicable
Skin sensitization --- Not Applicable
Germ cell mutagenicity --- Not Applicable
Carcinogenicity --- Not Applicable
Reproductive toxicity --- Not Applicable
STOT-single exposure 3 May cause drowsiness or dizziness.
STOT-repeated exposure --- Not Applicable
Aspiration hazard --- Not Applicable

SECTION 11 NOTES:

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:
The preparation has been assessed following the conventional method of the Dangerous Preparations Directive 1999/45/EC and GHS and is not classified as dangerous for the environment, but contains substance(s) dangerous for the environment.

Ingredient Isopropyl Alcohol (67-63-0)	96 hr LC50Fish, mg/l, 1400.00 Lepomis macrochirus 48 hr EC50 crustacea, mg/l , 100.00 Daphnnia magna ErC50 algae mg/l, 100.00 (72 hr) Soenedesmus subspicatus

SECTION 12 NOTES:
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 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Observe all federal, state and local regulations when disposing of this product.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION
PROPER SHIPPING NAME: ISOPROPANOL
HAZARD CLASS: N/A
DOT SHIPPING ID NUMBER: UN 1219
DOT PACKING GROUP: II
DOT HAZARD CLASS: 3
DOT LABEL STATEMENT: N/A

WATER TRANSPORTATION
PROPER SHIPPING NAME: ISOPROPANOL
HAZARD CLASS: 3
ID NUMBER: UN 1219
PACKING GROUP: II
LABEL STATEMENTS: N/A

AIR TRANSPORTATION
PROPER SHIPPING NAME: ISOPROPANOL
HAZARD CLASS: 3
ID NUMBER: UN 1219
PACKING GROUP: II
LABEL STATEMENTS: N/A

SECTION 14 NOTES: EMS-No: F-E, S-D
Small quantity Exception: 49CFR173.4
Execmption for US Ground Transportation: Limited Quantity

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 inventory.
CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A

SARA 311/312 HAZARD CATEGORIES: No chemicals at levels which require reporting under this statute.

SARA 313 REPORTABLE INGREDIENTS: Isopropyl Alcohol

STATE REGULATIONS:
Proposition 65 - Carcinogens (>0.0%):
No chemicals at levels which require reporting under this statute.
Proposition 65 - Developmental Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.
Proposition 65 - Female Repro Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.
Proposition 65 - Male Repro Toxins (>0.0%):
No chemicals at levels which require reporting under this statute.
New Jersey RTK Substances (>1%):
Isopropyl Alcohol
Pennsylvania RTK Substances (>1%):
Isopropyl Alcohol

SDS DATE: 8/7/2015

INTERNATIONAL REGULATIONS: WHMIS: B2 D2B

SECTION 15 NOTES:
EPCRA 302 Extremely Hazardous: No chemicals at levels which require reporting under this statute.

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.

MetriMist™
Date Prepared: 7/14/2015

MATERIAL SAFETY DATA SHEET

1. Product And Company Identification

Product Name: **MetriMist™**

Manufacturer: METREX™ RESEARCH
28210 Wick Road
Romulus, Michigan 48174
U.S.A.

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

Canadian Importer: VDI Health Care
250 First Gulf Boulevard
Brampton ON L6W4T5
Canada
(905) 796-3365
Fax: (905) 796-7818

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)
In Canada Canutec: 1 (613) 996-6666 (24 hours)

MSDS Date Of Preparation/Revision: 7/14/2015
Product Use: Aromatic Deodorizer.

2. Composition Information

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.

3. Hazard Identification

WHMIS: Not controlled under WHMIS.

Hazard Statements: NOT EXPECTED TO PRODUCE SIGNIFICANT ADVERSE HEALTH EFFECTS WHEN THE RECOMMENDED INSTRUCTIONS FOR USE ARE FOLLOWED.
Precautions: No known significant effects or critical hazards. Avoid prolonged contact with eyes, skin and clothing
Routes of Entry: Eye Contact. Inhalation.

Potential Acute Health Effects:
Inhalation: No known significant effects or critical hazards.
Ingestion: No known significant effects or critical hazards.
Skin: No known significant effects or critical hazards.
Eyes: No known significant effects or critical hazards.

Potential chronic health effects with Chronic Misuse of Product:

Chronic health effects: No known significant effects or critical hazards.
Target organs: No known significant effects or critical hazards.
Carcinogenicity Classification: 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.

4. Emergency First Aid Procedures

Skin: In case of irritation or redness, discontinue use and seek medical attention if the condition persists.

Eyes: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention immediately.

Inhalation: Remove to fresh air. If victim has stopped breathing, give artificial respiration. Get medical attention.

Ingestion: Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms persist.

Note to physician:
No specific treatment. Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

5. Fire Fighting Measures

Flammability of the product: Not flammable. In a fire or if heated, a pressure increase will occur and the container may burst.

Extinguishing Media:
Suitable: Carbon dioxide, dry chemical. Foam.
Special exposure hazards: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Hazardous thermal decomposition products: No specific data.

Special Fire Fighting Procedures: None.

6: Accidental Release Measures

Personal Precautions for Large Spill:
No action shall be taken involving any personal risk or without suitable training. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate.

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 for cleaning up significant spills:

Small spills:
Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container.

Large spills:
Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non- combustible, absorbent material such as sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

7. Handling and Storage

Precautions to be taken in Handling of Product: No special precautions necessary.

Precautions to be taken for Storage of Product: No special precautions necessary. Store in accordance with local regulations.

Other Precautions: Keep out of reach of children.

8. Exposure Controls / Personal Protection

Occupational exposure limits: No exposure limit value known.

Engineering measures: General ventilation is adequate.

Work/Hygiene Practices: Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure.

Personal Protection:
Hands: Latex rubber, butyl rubber, nitrile rubber and polyethylene.

Eye Protection: If risk assessment indicates safety eyewear is needed, safety eyewear complying with an approved standard should be used to avoid exposure to liquid splashes, mists or dusts.

Skin:	In case of irritation or redness, discontinue use and seek medical attention if the condition persists.
Respiratory:	A respirator is not needed under normal and intended conditions of product use.
Environmental exposure controls:	Not applicable.

9. Physical and Chemical Properties

Physical state:	Liquid.	**Evaporation Rate:**	Not available
Flash point:	Not available	**Relative density:**	1.004
Flammable Limits:	Not available	**Vapor pressure:**	Not available
Auto-ignition temperature:	Not available	**Vapor density:**	Not available
Color:	Not available	**pH:**	Not available
Odor:	Floral	**Viscosity:**	Not available
Specific Gravity (H20 = 1):	Not available		
Melting/freezing point:	Not available		
Boiling/condensation point:	100°C (212°F)		
Solubility:	Easily soluble in the following materials: cold water and hot water.		

10. Stability and Reactivity Data

Stability: The product is stable.
Conditions To Avoid: No specific data.
Incompatibility: Reactive or incompatible with the following materials: oxidizing materials, reducing materials, acids.
Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous decomposition will not occur.
Hazardous Polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur

11. Toxicological Information

Acute toxicity:	Not available.
Chronic Toxicity:	Not available.
Irritation/Corrosion:	Not available.
Sensitizer:	Not available.
Carcinogenicity Classification:	Not available.
Mutagenicity:	Not available.
Teratogenicity:	Not available.
Reproductive Toxicity:	Not available.

12. Ecological Information

Ecotoxicity: No known significant effects or critical hazards.

13. Disposal Considerations

Waste Disposal: 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.

14. Transport Information

TDG/IMDG/IATA: Not regulated.

15. Regulatory Information

NONE

16. Other Information

Note: 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.

Nitrogen, refrigerated liquid

Safety Data Sheet P-4630

This SDS conforms to U.S. Code of Federal Regulations 29 CFR 1910.1200, Hazard Communication.

Date of issue: 01/01/1979 Revision date: 10/21/2016 Supersedes: 10/03/2014

SECTION: 1. Product and company identification

1.1. Product identifier

Product form	:	Substance
Name	:	Nitrogen, refrigerated liquid
CAS No	:	7727-37-9
Formula	:	N2
Other means of identification	:	Nitrogen (cryogenic liquid), Nitrogen, Medipure Liquid Nitrogen

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

Use of the substance/mixture	:	Medical applications Industrial use Food applications

1.3. Details of the supplier of the safety data sheet

Praxair, Inc.
10 Riverview Drive
Danbury, CT 06810-6268 - USA
T 1-800-772-9247 (1-800-PRAXAIR) - F 1-716-879-2146
www.praxair.com

1.4. Emergency telephone number

Emergency number	:	Onsite Emergency: 1-800-645-4633 CHEMTREC, 24hr/day 7days/week — Within USA: 1-800-424-9300, Outside USA: 001-703-527-3887 (collect calls accepted, Contract 17729)

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

GHS-US classification

Refrigerated liquefied gas H281

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :

GHS04

Signal word (GHS-US)	:	WARNING
Hazard statements (GHS-US)	:	H281 - CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY OSHA-H01 - MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION
Precautionary statements (GHS-US)	:	P202 - Do not handle until all safety precautions have been read and understood P271+P403 - Use and store only outdoors or in a well-ventilated place P282 - Wear cold insulating gloves/face shield/eye protection. cold insulating gloves, face shield, eye protection CGA-PG05 - Use a back flow preventive device in the piping CGA-PG24 - DO NOT change or force fit connections CGA-PG06 - Close valve after each use and when empty CGA-PG23 - Always keep container in upright position

2.3. Other hazards

Other hazards not contributing to the	:	Asphyxiant in high concentrations

classification | Contact with liquid may cause cold burns/frostbite.

2.4. Unknown acute toxicity (GHS US)

No data available

SECTION 3: Composition/Information on ingredients

3.1. Substance

Name	Product identifier	%
Nitrogen, refrigerated liquid (Main constituent)	(CAS No) 7727-37-9	100

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove victim to uncontaminated area wearing self contained breathing apparatus. Keep victim warm and rested. Call a doctor. Apply artificial respiration if breathing stopped.

First-aid measures after skin contact : The liquid may cause frostbite. For exposure to liquid, immediately warm frostbite area with warm water not to exceed 105°F (41°C). Water temperature should be tolerable to normal skin. Maintain skin warming for at least 15 minutes or until normal coloring and sensation have returned to the affected area. In case of massive exposure, remove clothing while showering with warm water. Seek medical evaluation and treatment as soon as possible.

First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly. Contact an ophthalmologist immediately.. Get immediate medical attention.

First-aid measures after ingestion : Ingestion is not considered a potential route of exposure.

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

No additional information available

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

None.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Reactivity : No reactivity hazard other than the effects described in sub-sections below.

5.3. Advice for firefighters

Firefighting instructions : DANGER! Extremely cold liquid and gas under pressure. Take care not to direct spray onto vents on top of container. Do not discharge sprays directly into liquid; cryogenic liquid can freeze water rapidly

Evacuate all personnel from the danger area. Use self-contained breathing apparatus (SCBA) and protective clothing. Immediately cool containers with water from maximum distance. Stop flow of gas if safe to do so, while continuing cooling water spray. Remove ignition sources if safe to do so. Remove containers from area of fire if safe to do so. On-site fire brigades must comply with OSHA 29 CFR 1910.156 and applicable standards under 29 CFR 1910 Subpart L—Fire Protection.

Protection during firefighting : Compressed gas: asphyxiant. Suffocation hazard by lack of oxygen.

Special protective equipment for fire fighters : Use self-contained breathing apparatus. Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters.

Specific methods	:	Use fire control measures appropriate for the surrounding fire. Exposure to fire and heat radiation may cause gas containers to rupture. Cool endangered containers with water spray jet from a protected position. Prevent water used in emergency cases from entering sewers and drainage systems Exposure to fire may cause containers to rupture/explode Stop flow of product if safe to do so Use water spray or fog to knock down fire fumes if possible If leaking do not spray water onto container. Water surrounding area (from protected position) to contain fire.
Other information	:	Cryogenic liquid causes severe frostbite, a burn-like injury. Heat of fire can build pressure in a closed container and cause it to rupture. Venting vapors may obscure visibility. Air will condense on surfaces such as vaporizers or piping exposed to liquid or cold gas. Nitrogen, which has a lower boiling point than oxygen, evaporates first, leaving an oxygen-enriched condensate Containers are equipped with a pressure relief device. (Exceptions may exist where authorized by DOT.).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ensure adequate air ventilation. Wear self-contained breathing apparatus when entering area unless atmosphere is proven to be safe. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. Stop leak if safe to do so.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Try to stop release.

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

See also sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wear leather safety gloves and safety shoes when handling cylinders. Protect cylinders from physical damage; do not drag, roll, slide or drop. While moving cylinder, always keep in place removable valve cover. Never attempt to lift a cylinder by its cap; the cap is intended solely to protect the valve. When moving cylinders, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport cylinders. Never insert an object (e.g, wrench, screwdriver, pry bar) into cap openings; doing so may damage the valve and cause a leak. Use an adjustable strap wrench to remove over-tight or rusted caps. Slowly open the valve. If the valve is hard to open, discontinue use and contact your supplier. Close the container valve after each use; keep closed even when empty. Never apply flame or localized heat directly to any part of the container. High temperatures may damage the container and could cause the pressure relief device to fail prematurely, venting the container contents. For other precautions in using this product, see section 16.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a cool, well-ventilated place. Store and use with adequate ventilation. Store only where temperature will not exceed 125°F (52°C). Firmly secure containers upright to keep them from falling or being knocked over. Install valve protection cap, if provided, firmly in place by hand. Store full and empty containers separately. Use a first-in, first-out inventory system to prevent storing full containers for long periods

OTHER PRECAUTIONS FOR HANDLING, STORAGE, AND USE: When handling product under pressure, use piping and equipment adequately designed to withstand the pressures to be encountered. Never work on a pressurized system. Use a back flow preventive device in the piping. Gases can cause rapid suffocation because of oxygen deficiency; store and use with adequate ventilation. If a leak occurs, close the container valve and blow down the system in a safe and environmentally correct manner in compliance with all international, federal/national, state/provincial, and local laws; then repair the leak. Never place a container where it may become part of an electrical circuit.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Nitrogen, refrigerated liquid (7727-37-9)	
ACGIH	Not established
USA OSHA	Not established

8.2. Exposure controls

Appropriate engineering controls : Oxygen detectors should be used when asphyxiating gases may be released. Systems under pressure should be regularly checked for leakages. Provide adequate general and local exhaust ventilation. Consider work permit system e.g. for maintenance activities.

Hand protection : Wear working gloves when handling gas containers.

Eye protection : Wear safety glasses with side shields. Wear goggles and a face shield when transfilling or breaking transfer connections.

Respiratory protection : Self contained breathing apparatus (SCBA) or positive pressure airline with mask are to be used in oxygen-deficient atmospheres.

Thermal hazard protection : Wear cold insulating gloves. Wear cold insulating gloves when transfilling or breaking transfer connections.

Environmental exposure controls : None necessary.

Other information : Wear safety shoes while handling containers.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gas

Appearance : Colorless liquid.

Molecular mass : 28 g/mol

Color : Colorless liquid.

Odor : No odor warning properties.

Odor threshold : No data available

pH : Not applicable.

Relative evaporation rate (butyl acetate=1) : No data available

Relative evaporation rate (ether=1) : Not applicable.

Melting point : -210 °C

Freezing point : No data available

Boiling point : -195.8 °C

Flash point : No data available

Critical temperature : -149.9 °C

Auto-ignition temperature	:	Not applicable.
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapor pressure	:	Not applicable.
Critical pressure	:	3390 kPa
Relative vapor density at 20 °C	:	No data available
Relative density	:	0.8
Density	:	808.5 kg/m³ Liquid density at boiling point and 1 atm
Relative gas density	:	0.97
Solubility	:	Water: 20 mg/l
Log Pow	:	Not applicable.
Log Kow	:	Not applicable.
Viscosity, kinematic	:	Not applicable.
Viscosity, dynamic	:	Not applicable.
Explosive properties	:	Not applicable.
Oxidizing properties	:	None.
Explosion limits	:	No data available

9.2. Other information

Gas group	:	Refrigerated liquefied gas
Additional information	:	Gas/vapor 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

None.

10.4. Conditions to avoid

Avoid high temperatures, exposure to Lithium (Li), Neodymium (Nd), Titanium (Ti), Magnesium.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

Under certain conditions, nitrogen can react violently with lithium, neodymium, titanium (above 1472°F/800°C), and magnesium to form nitrides. At high temperature, it can also combine with oxygen and hydrogen.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified
Skin corrosion/irritation	:	Not classified pH: Not applicable.
Serious eye damage/irritation	:	Not classified pH: Not applicable.
Respiratory or skin sensitization	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified

Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No ecological damage caused by this product.

12.2. Persistence and degradability

Nitrogen, refrigerated liquid (7727-37-9)	
Persistence and degradability	No ecological damage caused by this product.

12.3. Bioaccumulative potential

Nitrogen, refrigerated liquid (7727-37-9)	
Log Pow	Not applicable.
Log Kow	Not applicable.
Bioaccumulative potential	No ecological damage caused by this product.

12.4. Mobility in soil

Nitrogen, refrigerated liquid (7727-37-9)	
Mobility in soil	No data available.
Ecology - soil	No ecological damage caused by this product.

12.5. Other adverse effects

Other adverse effects	:	Can cause frost damage to vegetation.
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

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations. Contact supplier for any special requirements.

SECTION 14: Transport information

In accordance with DOT

Transport document description	:	UN1977 Nitrogen, refrigerated liquid (cryogenic liquid), 2.2
UN-No.(DOT)	:	UN1977
Proper Shipping Name (DOT)	:	Nitrogen, refrigerated liquid cryogenic liquid
Class (DOT)	:	2.2 - Class 2.2 - Non-flammable compressed gas 49 CFR 173.115
Hazard labels (DOT)	:	2.2 - Non-flammable gas

DOT Special Provisions (49 CFR 172.102)	:	345 - "Nitrogen, refrigerated liquid (cryogenic liquid), UN1977" transported in open cryogenic receptacles with a maximum capacity of 1 L are not subject to the requirements of this subchapter. The receptacles must be constructed with glass double walls having the space between the walls vacuum insulated and each receptacle must be transported in an outer packaging with sufficient cushioning and absorbent materials to protect the receptacle from damage 346 - "Nitrogen, refrigerated liquid (cryogenic liquid), UN1977" transported in accordance with the requirements for open cryogenic receptacles in §173.320 and this special provision are not subject to any other requirements of this subchapter. The receptacle must contain no hazardous materials other than the liquid nitrogen which must be fully absorbed in a porous material in the receptacle T75 - When portable tank instruction T75 is referenced in Column (7) of the 172.101 Table, the applicable refrigerated liquefied gases are authorized to be transported in portable tanks in accordance with the requirements of 178.277 of this subchapter TP5 - For a portable tank used for the transport of flammable refrigerated liquefied gases or refrigerated liquefied oxygen, the maximum rate at which the portable tank may be filled must not exceed the liquid flow capacity of the primary pressure relief system rated at a pressure not exceeding 120 percent of the portable tank's design pressure. For portable tanks used for the transport of refrigerated liquefied helium and refrigerated liquefied atmospheric gas (except oxygen), the maximum rate at which the tank is filled must not exceed the liquid flow capacity of the pressure relief device rated at 130 percent of the portable tank's design pressure. Except for a portable tank containing refrigerated liquefied helium, a portable tank shall have an outage of at least two percent below the inlet of the pressure relief device or pressure control valve, under conditions of incipient opening, with the portable tank in a level attitude. No outage is required for helium

Additional information

Emergency Response Guide (ERG) Number	:	121 (UN1066);120 (UN1977)
Other information	:	No supplementary information available.
Special transport precautions	:	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 there is adequate ventilation. - 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.

Transport by sea

UN-No. (IMDG)	:	1977
Proper Shipping Name (IMDG)	:	NITROGEN, REFRIGERATED LIQUID
Class (IMDG)	:	2.2 - Non-flammable, non-toxic gases
MFAG-No	:	120

Air transport

UN-No. (IATA)	:	1977
Proper Shipping Name (IATA)	:	NITROGEN, REFRIGERATED LIQUID
Class (IATA)	:	2
Civil Aeronautics Law	:	Gases under pressure/Gases nonflammable nontoxic under pressure

SECTION 15: Regulatory information

15.1. US Federal regulations

Nitrogen, refrigerated liquid (7727-37-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Sudden release of pressure hazard

All components of this product are listed on the Toxic Substances Control Act (TSCA) inventory.

This product or mixture does not contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

Nitrogen, refrigerated liquid (7727-37-9)
Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

Nitrogen, refrigerated liquid (7727-37-9)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.2.2. National regulations

Nitrogen, refrigerated liquid (7727-37-9)
Listed on the AICS (Australian Inventory of Chemical Substances) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on the Korean ECL (Existing Chemicals List) Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on INSQ (Mexican National Inventory of Chemical Substances)

15.3. US State regulations

Nitrogen, refrigerated liquid(7727-37-9)	
U.S. - California - Proposition 65 - Carcinogens List	No
U.S. - California - Proposition 65 - Developmental Toxicity	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Female	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No
State or local regulations	U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

Other information : When you mix two or more chemicals, you can create additional, unexpected hazards. Obtain and evaluate the safety information for each component before you produce the mixture. Consult an industrial hygienist or other trained person when you evaluate the end product. Before using any plastics, confirm their compatibility with this product

Praxair asks users of this product to study this SDS and become aware of the product hazards and safety information. To promote safe use of this product, a user should (1) notify employees, agents, and contractors of the information in this SDS and of any other known product hazards and safety information, (2) furnish this information to each purchaser of the product, and (3) ask each purchaser to notify its employees and customers of the product hazards and safety information

The opinions expressed herein are those of qualified experts within Praxair, Inc. We believe that the information contained herein is current as of the date of this Safety Data Sheet. Since the use of this information and the conditions of use are not within the control of Praxair, Inc, it is the user's obligation to determine the conditions of safe use of the product

Praxair SDSs are furnished on sale or delivery by Praxair or the independent distributors and suppliers who package and sell our products. To obtain current SDSs for these products, contact your Praxair sales representative, local distributor, or supplier, or download from www.praxair.com. If you have questions regarding Praxair SDSs, would like the document number and date of the latest SDS, or would like the names of the Praxair suppliers in your area, phone or write the Praxair Call Center (Phone: 1-800-PRAXAIR/1-800-772-9247; Address: Praxair Call Center, Praxair, Inc, P.O. Box 44, Tonawanda, NY 14151-0044)

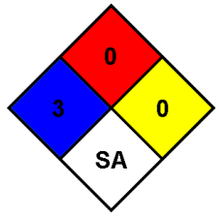
PRAXAIR and the Flowing Airstream design are trademarks or registered trademarks of Praxair Technology, Inc. in the United States and/or other countries.

NFPA health hazard : 3 - Short exposure could cause serious temporary or residual injury even though prompt medical attention was given.

NFPA fire hazard : 0 - Materials that will not burn.

NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

NFPA specific hazard : SA - This denotes gases which are simple asphyxiants.



HMIS III Rating

Health : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given

Flammability : 0 Minimal Hazard

Physical : 2 Moderate Hazard

SDS US (GHS HazCom 2012) - Praxair

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

YARAPRAXAIR	SAFETY DATA SHEET	Page : 1 / 9 Revised edition no : 1 Date : 31 / 1 / 2013 Supersedes : 0 / 0 / 0
	Oxygen	**YPX097A**

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]

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.

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.

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 regularily) 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.

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 shoud be regularily 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.

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.

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)

Yara Praxair AS
Postboks 23 Haugenstua, N-0915 Oslo, NORWAY
Tel. +47 04277
E-mail: norge@yarapraxair.com

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

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 commisssion 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

Yara Praxair AS
Postboks 23 Haugenstua, N-0915 Oslo, NORWAY
Tel. +47 04277
E-mail: norge@yarapraxair.com

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

SAFETY DATA SHEET

Professional Lysol®l Brand III Kills 99.9% of Viruses & Bacteria** Disinfectant Spray, All Scents

1. Product and company identification

Product name : Professional Lysol®l 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

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.

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)

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.

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/m³ 8 hours. **NIOSH REL (United States, 10/2013).** TWA: 1000 ppm 10 hours. TWA: 1900 mg/m³ 10 hours. **OSHA PEL (United States, 2/2013).** TWA: 1000 ppm 8 hours. TWA: 1900 mg/m³ 8 hours.
butane	**OSHA PEL 1989 (United States, 3/1989).** TWA: 800 ppm 8 hours. TWA: 1900 mg/m³ 8 hours. **NIOSH REL (United States, 10/2013).** TWA: 800 ppm 10 hours. TWA: 1900 mg/m³ 10 hours. **ACGIH TLV (United States, 6/2013).** STEL: 1000 ppm 15 minutes.

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.

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/cm³ [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.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethyl alcohol	LC50 Inhalation Vapor	Rat	124700 mg/m³	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

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.

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 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.

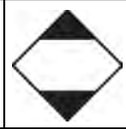
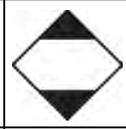
Other adverse effects : No known significant effects or critical hazards.

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.

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	AEROSOLES	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

Composition/information on ingredients

No products were found.

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.

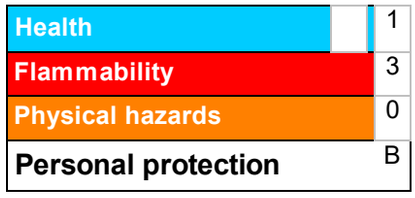
Keep out of the reach of children.
CONTENTS UNDER PRESSURE. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120 °F. Keep away from heat, sparks, open flames and hot surfaces. - No smoking.

Hazard statements :

Flammable

16. Other information

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



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.

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

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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.

16. Other information

RB is a member of the CSPA Product Care Product Stewardship Program.

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Promethazine HCl Injection, USP

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.

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 protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

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

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 properties

Appearance

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.

SAFETY DATA SHEET

Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

1. IDENTIFICATION

Product Identifier:	Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%
Synonyms:	Proxymetacaine hydrochloride
National Drug Code (NDC):	17478-263-12
Recommended Use:	Pharmaceutical. Proparacaine Hydrochloride Ophthalmic Solution is indicated for topical anesthesia in ophthalmic practice.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards: Not classified.

Health Hazards: Skin Sensitization — Category 1B

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H317 May cause an allergic skin reaction.

Precautionary Statement(s):

P261 Avoid breathing vapor or spray.

P264 Wash hands thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of workplace.

P280 Wear protective gloves/ protective clothing/ eye protection and face protection.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical attention.

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical attention.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Proparacaine Hydrochloride	Proxymetacaine hydrochloride	5875-06-9	$C_{16}H_{26}N_2O_3$•HCl	330.86	0.5%

The formula also contains the following inactive ingredients: Benzalkonium Chloride, 0.01%, Glycerin, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH between 3.5 to 6.0 and Water for Injection.

4. FIRST AID MEASURES

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical

	attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	May cause irritation to eyes, skin and respiratory tract. Can cause hypersensitivity (anaphylactic) in some individuals. Effects include excitation of the central nervous system (yawning, restlessness, dizziness, blurred vision, nausea, vomiting, muscle twitching, and convulsions), respiratory failure, cardiac arrhythmias, cardiac arrest and coma.
Medical Conditions Aggravated by Exposure:	Individuals sensitive to ester-type local anesthetics (e.g. butacaine, butamben, chloroprocaine, tetracaine, propoxycaine) or to PABA may be hypersensitive to proparacaine.
Notes to Physician:	Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or foam as necessary.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products:	None.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment and Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Refrigerate at 2° to 8°C (36° to 46°F). Keep bottle tightly closed. Store in carton until is empty to protect from light. If solution shows more than a faint yellow color, it should not be used. Store according to label and/or product insert information.

Specific End Use: Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Proparacaine Hydrochloride	Not established	Not established

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Respiratory protection is normally not required during intended product use. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Eye protection is normally not required during intended product use. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Hand protection is normally not required during intended product use. Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand

	contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
General Hygiene Considerations:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear, colorless aqueous solution.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	3.5 to 6.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	Nonflammable, noncombustible.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Freely soluble in water.
Partition Coefficient	No data available.
(n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Extreme heat or cold. Do not freeze. Protect from light and heat.
Incompatible Materials:	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: No data available.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: May cause irritation and hypersensitivity.

Ingestion: Moderately toxic by ingestion; However, very large quantities may induce yawning, restlessness, dizziness, blurred vision, nausea, vomiting, muscle twitching, convulsions, respiratory failure, cardiac arrhythmias or arrest and coma.

Skin Contact: May cause irritation and hypersensitivity in some individuals. Allergic contact dermatitis with drying and fissuring of the fingertips can occur.

Eye Contact: May cause temporary stinging, burning, and conjunctival redness. In the unlikely event irritation occurs it is most likely several hours after installation. After installation do not rub eye. The surface of the eye is in sensitive and can be scratched without feeling it. Although exceedingly rare, ophthalmic applications of Proparacaine can cause central nervous system stimulation followed by depression. A rare, severe, immediate allergic corneal reaction has been reported, characterized by acute diffuse filament formation and/or sloughing of large areas of dead skin, swelling and inflammation of the iris.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Proparacaine Hydrochloride	Mouse	Subcutaneous	LD_{50}	64 mg/kg
Proparacaine Hydrochloride	Mouse	Intravenous	LD_{50}	3,371 mcg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

AKORN

SAFETY DATA SHEET

Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

Repeated Does Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available
No data available	No data available	No data available	No data available
No data available	No data available	No data available	No data available

Aspiration Hazard: None anticipated from normal handling of this product.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: Based on clinical use, possible target organs include the nervous system.

Reproductive Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with Proparacaine Hydrochloride Ophthalmic Solution.

Carcinogenicity: Long term studies in animals have not been performed to evaluate the carcinogenic potential.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No applicable bioaccumulation is expected in the environment.

Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Proparacaine Hydrochloride	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Proparacaine Hydrochloride	Not Listed	Not Listed	Not Listed

California Proposition 65: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Silvadene Cream (Silver sulfadiazine)

Trade Name: SILVADENE
Chemical Family: Sulfonamide

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

Intended Use: Pharmaceutical product used as antimicrobial

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Propylene glycol	57-55-6	200-338-0	Not Listed	*

3. COMPOSITION / INFORMATION ON INGREDIENTS

White petrolatum	8009-03-8	232-373-2	Not Listed	*
Stearyl Alcohol	112-92-5	204-017-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
Silver sulfadiazine	22199-08-2	244-834-5	Not Listed	1
Sorbitan monooleate	1338-43-8	215-665-4	Not Listed	*
Isopropyl myristate	110-27-0	203-751-4	Not Listed	*
PEG-40 Stearate	9004-99-3	Not Listed	Not Listed	*
Water, purified	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.

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

Advice for Fire-Fighters

During all firefighting 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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

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

Silver sulfadiazine

Pfizer OEL TWA-8 Hr:	2000µg/m^3

Propylene glycol

Australia TWA	150 ppm 474 mg/m^3 10 mg/m^3
Ireland OEL - TWAs	150 ppm 470 mg/m^3 10 mg/m^3
Latvia OEL - TWA	7 mg/m^3
Lithuania OEL - TWA	7 mg/m^3

White petrolatum

ACGIH Threshold Limit Value (TWA)	5 mg/m^3 (oil mist, mineral)
ACGIH Threshold Limit Value (STEL)	10 mg/m^3 (oil mist, mineral)

Stearyl Alcohol

Germany - TRGS 900 - TWAs	20 ppm 224 mg/m^3

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.)
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:	Cream	**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
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

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

Silver sulfadiazine
No data available

Water, purified
No data available

Methylparaben
No data available

Isopropyl myristate
No data available

Sorbitan monooleate
No data available

PEG-40 Stearate
No data available

Propylene glycol
No data available

White petrolatum
No data available

Stearyl 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

Flammablity:

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:	Contact with sulfonamides may cause dermatitis. Allergic skin reaction may occur based on effects of other sulfonamides. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.
Known Clinical Effects:	As in all sulfonamide therapy, the following reactions may occur including nausea, vomiting, diarrhea, inflammation of the liver and pancreas, blood disorder, drug fever, skin rash, infection of the conjunctiva and sclera, blood in the urine and crystalluria.

Acute Toxicity: (Species, Route, End Point, Dose)

Silver sulfadiazine
Rat Oral LD50 > 10 g/kg

Isopropyl myristate
Mouse Oral LD50 49,700 mg/kg
Rabbit Dermal LD50 5000 mg/kg

PEG-40 Stearate
Rat Oral LD50 > 20,000 mg/kg

Propylene glycol
Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/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.

11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Stearyl Alcohol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Silver sulfadiazine
Embryo / Fetal Development Rabbit Oral Dose not specified NOAEL Not teratogenic

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

Silver sulfadiazine
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Silver sulfadiazine
24 Month(s) Rat Dermal NOAEL Not carcinogenic
18 Month(s) Mouse Dermal NOAEL Not carcinogenic

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.

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.

15. REGULATORY INFORMATION

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

Methylparaben

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	202-785-7

Silver sulfadiazine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	244-834-5

Sorbitan monooleate

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	215-665-4

Isopropyl myristate

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
EU EINECS/ELINCS List	203-751-4

Propylene glycol

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	200-338-0

PEG-40 Stearate

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

White petrolatum

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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 28.
REACH - Carcinogens Category 2:	Present
EU EINECS/ELINCS List	232-373-2

Stearyl 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	204-017-6

Water, purified

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

Additional Information: White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

16. OTHER INFORMATION

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 16 - Other Information.
Revision date:	07-Nov-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

SAFETY DATA SHEET

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

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

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

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

Other Hazards No data available
Australian Hazard Classification (NOHSC): 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.

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

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/m^3, 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.

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

Flammablity:

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

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

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.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS 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

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
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Testosterone Cypionate Injection, USP C-III

WEST-WARD PHARMACEUTICALS

Section 1. Identification

GHS product identifier : Testosterone Cypionate Injection, USP C-III

Synonyms : Not available.

Product code : NDC 0143-9659-01 NDC 0143-9726-01

Chemical family : Not available.

Product type : Pharmaceutical

Container information : 1 mL vial, 10 mL vial

Identified uses : Hormone.

Supplier's details : West-Ward Pharmaceuticals
401 Industrial Way
Eatontown NJ 07724
Phone (732 542 1191)
Fax (732 720 6220)

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 : CARCINOGENICITY - Category 1B
TOXIC TO REPRODUCTION (Fertility) - Category 2
TOXIC TO REPRODUCTION (Unborn child) - Category 2
AQUATIC HAZARD (LONG-TERM) - Category 3

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H350 - May cause cancer.
H361 - Suspected of damaging fertility or the unborn child.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves. Wear eye or face protection. Wear protective clothing.
P273 - Avoid release to the environment.

Response : P308 + P313 - IF exposed or concerned: Get medical attention.

Storage : P405 - Store locked up.

Section 2. Hazards identification

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

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.

Ingredient name	%	CAS number
Testosterone Cypionate	10 - 30	58-20-8
Benzyl benzoate	10 - 30	120-51-4
Cottonseed oil	30 - 60	8001-29-4
Benzyl Alcohol	0.1 - 1	100-51-6

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.

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 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. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. 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. 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

Section 4. First aid measures

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.

Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

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. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. 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

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

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. 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). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Avoid release to the environment. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. 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. Store locked up. 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 : 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.

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

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 properties

Appearance

Physical state : Liquid.

Color : Clear to Yellow.

Odor : Not available.

Odor threshold : Not available.

pH : Not available.

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Section 9. Physical and chemical properties

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.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials, reducing 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

Product/ingredient name	Result	Species	Dose	Exposure
Benzyl benzoate	LD50 Dermal LD50 Oral	Rabbit Rat	4 g/kg 2800 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.

Section 11. Toxicological information

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 : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

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 : May cause cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : Suspected of damaging the unborn child.

Developmental effects : No known significant effects or critical hazards.

Section 11. Toxicological information

Fertility effects : Suspected of damaging fertility.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral Dermal	2500 mg/kg 20000 mg/kg

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Benzyl benzoate	3.97	-	low

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	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

Classification : Delayed (chronic) health hazard

Section 15. Regulatory information

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Benzyl benzoate	≥10 - <25	No.	No.	No.	Yes.	No.
Testosterone Cypionate	≥10 - <25	No.	No.	No.	No.	Yes.

SARA 313

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: Cottonseed Oil; Testosterone esters

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Testosterone Cypionate	No.	Yes.	No.	No.

Section 16. Other information

History

Date of issue mm/dd/yyyy : 09/16/16

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

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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.